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Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years (Review)

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[Intervention Review]

Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

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ABSTRACT

Background

Child overweight and obesity has increased globally, and can be associated with short- and long-term health consequences.

Objectives

To assess the effects of diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.

Search methods

We performed a systematic literature search in the databases Cochrane Library, MEDLINE, EMBASE, PsycINFO, CINAHL, and LILACS, as well as in the trial registers ClinicalTrials.gov and ICTRP Search Portal. We also checked references of identified trials and systematic reviews. We applied no language restrictions. The date of the last search was March 2015 for all databases.

Selection criteria

We selected randomised controlled trials (RCTs) of diet, physical activity, and behavioural interventions for treating overweight or obesity in preschool children aged 0 to 6 years.

Data collection and analysis

Two review authors independently assessed risk of bias, evaluated the overall quality of the evidence using the GRADE instrument, and extracted data following the *Cochrane Handbook for Systematic Reviews of Interventions*. We contacted trial authors for additional information.

Main results

We included 7 RCTs with a total of 923 participants: 529 randomised to an intervention and 394 to a comparator. The number of participants per trial ranged from 18 to 475. Six trials were parallel RCTs, and one was a cluster RCT. Two trials were three-arm trials, each comparing two interventions with a control group. The interventions and comparators in the trials varied. We categorised the comparisons into two groups: multicomponent interventions and dietary interventions. The overall quality of the evidence was low or very low, and six trials had a high risk of bias on individual 'Risk of bias' criteria. The children in the included trials were followed up for between six months and three years.

In trials comparing a multicomponent intervention with usual care, enhanced usual care, or information control, we found a greater reduction in body mass index (BMI) z score in the intervention groups at the end of the intervention (6 to 12 months): mean difference (MD) -0.3 units (95% confidence interval (CI) -0.4 to -0.2); P < 0.00001; 210 participants; 4 trials; low-quality evidence, at 12 to 18 months' follow-up: MD -0.4 units (95% CI -0.6 to -0.2); P = 0.0001; 202 participants; 4 trials; low-quality evidence, and at 2 years' follow-up: MD -0.3 units (95% CI -0.4 to -0.1); 96 participants; 1 trial; low-quality evidence.

One trial stated that no adverse events were reported; the other trials did not report on adverse events. Three trials reported health-related quality of life and found improvements in some, but not all, aspects. Other outcomes, such as behaviour change and parent-child relationship, were inconsistently measured.

One three-arm trial of very low-quality evidence comparing two types of diet with control found that both the dairy-rich diet (BMI z score change MD -0.1 units (95% CI -0.11 to -0.09); P < 0.0001; 59 participants) and energy-restricted diet (BMI z score change MD -0.1 units (95% CI -0.11 to -0.09); P < 0.0001; 57 participants) resulted in greater reduction in BMI than the comparator at the end of the intervention period, but only the dairy-rich diet maintained this at 36 months' follow-up (BMI z score change in MD -0.7 units (95% CI -0.71 to -0.69); P < 0.0001; 52 participants). The energy-restricted diet had a worse BMI outcome than control at this follow-up (BMI z score change MD 0.1 units (95% CI 0.09 to 0.11); P < 0.0001; 47 participants). There was no substantial difference in mean daily energy expenditure between groups. Health-related quality of life, adverse effects, participant views, and parenting were not measured.

No trial reported on all-cause mortality, morbidity, or socioeconomic effects.

All results should be interpreted cautiously due to their low quality and heterogeneous interventions and comparators.

Authors' conclusions

Muticomponent interventions appear to be an effective treatment option for overweight or obese preschool children up to the age of 6 years. However, the current evidence is limited, and most trials had a high risk of bias. Most trials did not measure adverse events. We have identified four ongoing trials that we will include in future updates of this review.

The role of dietary interventions is more equivocal, with one trial suggesting that dairy interventions may be effective in the longer term, but not energy-restricted diets. This trial also had a high risk of bias.

PLAIN LANGUAGE SUMMARY

Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Review question

How effective are diet, physical activity, and behavioural interventions in reducing the weight of overweight and obese preschool children?

Background

Across the world more children are becoming overweight and obese. These children are more likely to suffer from health problems, both while as children and in later life. More information is needed about what works best for treating this problem.

Study characteristics

We found 7 randomised controlled trials (clinical studies where people are randomly put into one of two or more treatment groups) comparing diet, physical activity, and behavioural (where habits are changed or improved) treatments (interventions) to a variety of

control groups (who did not receive treatment) delivered to 923 overweight or obese preschool children up to the age of 6 years. We grouped the studies by the type of intervention. Our systematic review reported on the effects of multicomponent interventions and dietary interventions compared with no intervention, 'usual care', enhanced usual care, or some other therapy if it was also delivered in the intervention arm. The children in the included studies were monitored (called follow-up) for between six months and three years.

Key results

Most studies reported the body mass index (BMI) z score: BMI is a measure of body fat and is calculated by dividing weight (in kilograms) by the square of the body height measured in metres (kg/m^2). In children, BMI is often measured in a way that takes into account sex, weight, and height as children grow older (BMI z score). We summarised the results of 4 trials in 202 children reporting the BMI z score, which on average was 0.4 units lower in the multicomponent intervention groups compared with the control groups. Lower units indicate more weight loss. For example, a 5-year-old girl with a body height of 110 cm and a body weight of 32 kg has a BMI of 26.4 and a BMI z score of 2.99. If this girl loses 2 kg weight within a year (and gained 1 cm in height), she would have reduced her BMI z score by approx. 0.4 units (her BMI would be 24.3 and her BMI z score 2.58). Accordingly, the average change in weight in the multicomponent interventions was 2.8 kg lower than in the control groups. Other effects of the interventions, such as improvements in health-related quality of life or evaluation of the parent-child relationship, were less clear, and most studies did not measure adverse events. No study investigated death from any cause, morbidity, or socioeconomic effects. One study found that BMI z score reduction was greater at the end of both dairy-rich and energy-restricted dietary interventions compared with a healthy lifestyle education only. However, only the dairy-rich diet continued to show benefits two to three years later, whereas the energy-restricted diet group had a greater increase in BMI z score than the control group.

This evidence is up to date as of March 2015.

Quality of the evidence

The overall quality of the evidence was low or very low, mainly because there were just a few studies per outcome measurement or the number of the included children was small. In addition, many children left the studies before they had finished.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children aged 0 to 6 years

Population: preschool children (aged 0 to 6 years) with overweight or obesity
Settings: various
Intervention: multicomponent interventions
Comparison: usual care/enhanced usual care/information control/wait-list control

Outcomes	Control	Multicomponent intervention	Relative effect (95% CI)	No of participants (trials)	Quality of the evidence (GRADE)	Comments
Changes in BMI and body weight **a. BMI z score**[a] **[units]** Follow-up: 12 to 18 months **b. Weight [kg]** Follow-up: 12 to 18 months	a. The mean change in BMI z score ranged across control groups from -0.3 units to +0.4 units b. The mean change in weight ranged across control groups from +3.1 kg to +5.2 kg	b. The mean change in BMI z score in the intervention groups was **0.4 units lower (0.6 to 0.2 lower)** b. The mean change in weight in the intervention group was **2.8 kg lower (4.4 to 1.2 lower)**	-	a. 202 (4) b. 202 (4)	a. ⊕⊕◯◯ **low**[b] b. ⊕⊕◯◯ **low**[b]	Lower units indicate more weight loss
Adverse events Follow-up: 24 months	See comment	See comment	See comment	88 (1)	⊕◯◯◯ **very low**[c]	Only 1 trial (abstract only) reported on adverse events, stating no adverse events were observed
HrQoL and self esteem **a. DUX 25** (Dutch Child AZL TNO Quality-of-Life tool: total score and 4 domains; scale 0 to 100; higher score indicates better HrQoL) Follow-up: 12 months **b. CHQ-PF50** (Dutch edition of the Child Health Questionnaire Par-	See comment	See comment	See comment	a. 40 (1) b. 40 (1) c. 17 (1) d. 16 (1)	a/b/c/d ⊕◯◯◯ **very low**[c]	No trials reported self esteem a. Change in median of the total score: +5 in the intervention group versus -5 in the control group; change in median of 1 of 4 domains (physical functioning): +8 in the intervention group versus -4

ent Form: 15 items; score 0 to 100; higher score indicates better HrQoL) Follow-up: 12 months **c. PedsQL** (Pediatric Quality of Life Inventory, physical functioning subscale; higher score indicates better HrQoL) Follow-up: 6 months/12 months **d. PedsQL** (total score) Follow-up: 12 months						in the control group b. No statistically significant differences in any of the 15 items c. 6 months' change in mean: +9.5 units in the intervention group versus -1.7 units in the control group, data not reported for total score and 3 other subscales; 12 months' change in mean +13.8 units in the intervention group versus -2.7 units in the control group, data not reported for total score and 3 other subscales d. No substantial differences between multicomponent intervention and control group
All-cause mortality	See comment	See comment	See comment	See comment	See comment	No trials reported all-cause mortality
Morbidity	See comment	See comment	See comment	See comment	See comment	No trials reported morbidity
Parent-child relationship or assessment of parenting (CFQ - Child Feeding Questionnaire: 31 items)	See comment	See comment	See comment	44 (2)	⊕◯◯◯ **very low**[c]	Limited data were reported, no substantial differences between intervention and control groups
Socioeconomic effects	See comment	See comment	See comment	See comment	See comment	No trials reported socioeconomic effects

BMI: body mass index; **CI:** confidence interval; **HrQoL :** health-related quality of life

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[a]' ' A BMI z score or standard deviation score indicates how many units (of the standard deviation) a child's BMI is above or below the average BMI value for their age group and sex. For instance, a z score of 1.5 indicates that a child is 1.5 standard deviations above the average value, and a z score of -1.5 indicates a child is 1.5 standard deviations below the average value" (NOO NHS 2011).
[b]Downgraded by two levels because of risk of bias (reporting bias), imprecision, and indirectness; see Appendix 9.
[c]Downgraded by three levels because of serious risk of bias (performance bias, detection bias, reporting bias) and imprecision (small number of trials and participants); see Appendix 9.

BACKGROUND

The prevalence of overweight and obese children and adolescents has increased throughout the world, presenting a global public health crisis (Ng 2014; WHO 2015a). Although once considered to be a condition affecting only high-income countries, rates of paediatric overweight and obesity have recently started to rise dramatically in some low- and middle-income countries (Wang 2012). Using the International Obesity Task Force (IOTF) standard definition, the age-standardised prevalence of overweight and obesity in children and adolescents has increased in low-, middle-, and high-income countries over the last 30 years (Cole 2000). In 2013, the prevalence of overweight and obese children and adolescents in high-income countries was estimated at 23.8% (95% confidence interval (CI) 22.9 to 24.7) for boys and 22.6% (95% CI 21.7 to 23.6) for girls. In low- and middle-income countries, the prevalence was estimated as 12.9% (95% CI 12.3 to 13.5) of boys and 13.4% (95% CI 13 to 13.9) of girls (Ng 2014). Very young children are also affected. In 2010, de Onis 2010 used the World Health Organization growth standards to estimate that over 42 million children under 5 years of age were overweight or obese, with approximately 35 million of these children living in low- and middle-income countries (WHO 2015b).

Inequalities in overweight and obesity prevalence have also been documented. Generally, socioeconomically disadvantaged children in high-income countries (Knai 2012; NCB 2015; Shrewsbury 2008), and children of higher socioeconomic status in low- and middle-income countries (Lobstein 2004; Wang 2012), are at greater risk of becoming overweight. However, this relationship may vary by population demographics (for example age, gender, ethnicity), and environment (for example country, urbanisation) (Wang 2012). The prevalence of obesity has been shown to vary by ethnicity, with large data sets showing substantial ethnic variation in English (HSCIC 2015), American (Freedman 2006; Skinner 2014), and New Zealand (Rajput 2014) child populations.

Whilst there is some evidence that the rate of increase in paediatric obesity may be slowing in some high-income countries, current levels remain too high, and continue to rise in many low- and middle-income countries (Olds 2011; Rokholm 2010). However, an additional concern in some high-income countries such as the USA, in Kelly 2013 and Skinner 2014, and England, in CMO 2015 and Ells 2015, is the rise in severe paediatric obesity. Whilst the IOTF published an international definition for severe paediatric (morbid) obesity in 2012 (Cole 2012), often severe obesity prevalence is reported using country-specific cut points, making international comparisons difficult. However, data from the USA, in Skinner 2014, and England, in Ells 2015, has shown that the prevalence of severe paediatric obesity varies by socioeconomic status and ethnicity, and may result in a greater risk of adverse cardiometabolic events and severe obesity in adulthood (Kelly 2013).

Description of the condition

Childhood overweight and obesity results from an accumulation of excess body fat, and can increase the risk of both short- and longer-term health consequences. Numerous obesity-related comorbidities can develop during childhood, which include muscular skeletal complaints (Paulis 2014); cardiovascular risk factors such as hypertension, insulin resistance, and hyperlipidaemia (Reilly 2003), even in very young children (Bocca 2013); motor and developmental delays (Cataldo 2015); and conditions such as such as sleep apnoea (Narang 2012), asthma (Egan 2013), liver disease, and type 2 diabetes (Daniels 2009; Lobstein 2004). The condition can also affect psychosocial well-being, with obese young people susceptible to reduced self esteem and quality of life (Griffiths 2010), as well as stigmatisation (Puhl 2007; Tang-Peronard 2008). Evidence also shows that childhood obesity can track into adulthood (Parsons 1999; Singh 2008; Whitaker 1997), and is therefore associated with an increased risk of ill health later in life (Reilly 2011).

Description of the intervention

Given the serious implications associated with childhood and adolescent obesity, effective treatment is imperative. Whilst the fundamental principles of weight management in children and adolescents are the same as in adults (that is reduced energy intake and increased energy expenditure), the primary aim of treatment (that is weight reduction or deceleration of weight gain) and the most suitable intervention approach vary, and are dependent on the child's age and degree of excess weight, among other considerations. Family-based interventions combining dietary, physical activity, and behavioural components have been shown to be effective and are considered the current best practice in the treatment of childhood obesity in children under 12 years of age (Oude Luttikhuis 2009).

Adverse effects of the intervention

It is not anticipated that diet, physical activity, and behavioural interventions will lead to adverse outcomes. However, as with all obesity treatment interventions in children and young people, potential adverse effects should be considered, including effects on linear growth, eating disorders and psychological well-being.

How the intervention might work

The home environment is important in the aetiology of childhood obesity, with parents playing a large role in food choice and physical activity for their children. In surveys in the USA, Wansink estimated that the 'nutritional gatekeeper' (who buys and cooks the food) controls 72% of the food eaten by children, both within and outside the home (Wansink 2006). A systematic review by Clark et al. showed that a high level of parental restriction of snack

foods is associated with increased energy intake and weight gain in children (Clark 2007). In contrast, 'covert' control of children's food intake by controlling the home eating environment to limit exposure to unhealthy foods (that is not buying unhealthy foods) is shown to lower the intake of unhealthy snacks when compared with 'overt' control (that is buying the snacks but not allowing access) (Ogden 2006). In terms of physical activity, a systematic review showed that parental support is strongly associated with physical activity levels in children, albeit the influence of parental modelling by being physically active themselves was inconsistent (Gustafson 2006).

Poor family functioning, such as poor communication and high levels of conflict, is also associated with higher risk of obesity in children (Halliday 2014). Authoritative parenting style is associated with lower risk of obesity in children, when compared with other parenting styles (Sleddens 2011). Due to the importance of the role of parents in the home environment and the importance of parenting styles and skills, parents have been defined as the 'agents of change' in the family for intervening with children under 12 years of age who are obese (Golan 2004). In addition, young children themselves are receptive to early and fact-based health education (Baxter 2015). Qualitative research suggests that interventions for preschool-aged children should aim to promote parental modelling of positive behaviours, create home and preschool environments that promote healthy diets, and simultaneously target factors at the family and preschool/childcare levels (Paes 2015).

Why it is important to do this review

The first version of this systematic review was published in 2003 and included analysis of childhood obesity treatment trials published up until July 2001 (Summerbell 2003). The second version was published in 2009, updating the 2003 review (Oude Luttikhuis 2009).

To reflect the rapid growth in this field, the third update to this review has been split across six reviews focusing on the following treatment approaches: surgery; drugs; parent-only interventions; diet, physical activity, and behavioural interventions for young children aged 0 to 6 years; schoolchildren aged 6 to 11 years; and adolescents aged 12 to 17 years.

The current review examines the effectiveness of interventions for preschool children aged up to 6 years. Previous systematic reviews identified an absence of randomised controlled trials assessing interventions for preschool-aged children (Bluford 2007; Bond 2009; Bond 2011; Oude Luttikhuis 2009), however a number of trials have since been published.

The results of this current review and other systematic reviews in this series will provide information on which to underpin clinical guidelines and health policy on the treatment of childhood obesity.

OBJECTIVES

To assess the effects of diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled clinical trials with at least six months of follow-up.

Types of participants

We included trials of overweight or obese children with a mean trial age of 0 to 6 years at the commencement of the intervention. We excluded the critically ill, or children with a syndromic cause for their obesity (for example Prader-Willi).

Types of interventions

We planned to investigate the following comparisons of intervention versus control/comparator.

Intervention

Any form of lifestyle intervention with a primary aim to treat overweight or obesity in children (any form of dietary, physical activity and/or behavioural therapy delivered as single- or multicomponent interventions).

Comparator

The comparison could be no intervention, usual care (however defined), or an alternative concomitant therapy providing it is delivered in the intervention arm.

Concomitant interventions had to be the same in the intervention and comparator groups to establish fair comparisons.

Types of outcome measures

Primary outcomes

1. Changes in body mass index (BMI) and body weight.
2. Adverse events.

Secondary outcomes

1. Health-related quality of life and self esteem.
2. All-cause mortality.
3. Morbidity.
4. Anthropometric measures other than BMI.
5. Behaviour change.
6. Participant views of the intervention.
7. Parent-child relationship or assessment of parenting.
8. Socioeconomic effects by validated measures.

Method and timing of outcome measurement

- Changes in BMI (kg/m²) and body weight (kg): measured at baseline and at least at six months.
- Adverse events: defined as an adverse outcome that occurred during or after the intervention but is not necessarily caused by it, and measured at baseline and at least at six months.
- Health-related quality of life: evaluated by a validated instrument such as Pediatric Quality of Life Inventory and measured at baseline and at least six months.
- All-cause mortality: defined as any death that occurred during or after the intervention and measured at six months or later.
- Morbidity: defined as illness or harm associated with the intervention and measured at baseline and six months or later.
- Anthropometric measures other than change in BMI: defined by the use of validated tools such as waist circumference, skin fold thickness, waist-to-hip ratio, dual X-ray absorptiometry, or bioelectrical impedance analysis and measured at baseline and at least at six months.
- Behaviour change: defined as validated measures of diet and physical activity and measured at baseline and at least at six months.
- Participant views of the intervention: defined as documented accounts from participant feedback and measured at baseline and at least at six months.
- Parent-child relationship or assessment of parenting: evaluated by a validated instrument and measured at baseline and at least at six months.
- Socioeconomic effects: defined as a validated measure of socioeconomic status such as parental income or educational status and measured at baseline and at least at six months.

Summary of findings

We present a 'Summary of findings' table in which we reported the following outcomes, listed according to priority.

1. Changes in BMI and body weight.
2. Adverse events.
3. Health-related quality of life.
4. All-cause mortality.
5. Morbidity.
6. Parent-child relationship or assessment of parenting.
7. Socioeconomic effects.

Search methods for identification of studies

Electronic searches

We searched the following sources from inception of each database to 10 March 2015 and placed no restrictions on the language of publication.

- Cochrane Library
  - Cochrane Database of Systematic Reviews (Issue 3, 2015)
  - Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 2, 2015)
  - Database of Abstracts of Reviews of Effects (DARE) (Issue 1, 2014)
  - Health Technology Assessment (HTA) Database (Issue 1, 2014)
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
- EMBASE <1974 to 2015 March 09>
- PsycINFO <1806 to March Week 1 2015>
- CINAHL
- LILACS
- ClinicalTrials.gov
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/), including:
  - Australian New Zealand Clinical Trials Registry (2 March 2015)
  - Chinese Clinical Trial Registry (2 March 2015)
  - EU Clinical Trials Register (EU-CTR) (2 March 2015)
  - ISRCTN (2 March 2015)
  - The Netherlands National Trial Register (2 March 2015)
  - Brazilian Clinical Trials Registry (2 February 2015)
  - Clinical Trials Registry - India (2 March 2015)
  - Clinical Research Information Service - Republic of Korea (3 March 2015)
  - Cuban Public Registry of Clinical Trials (3 March 2015)
  - German Clinical Trials Register (3 March 2015)
  - Iranian Registry of Clinical Trials (3 March 2015)
  - Japan Primary Registries Network (3 March 2015)
  - Pan African Clinical Trial Registry (3 March 2015)
  - Sri Lanka Clinical Trials Registry (2 March 2015)
  - Thai Clinical Trials Register (3 March 2015)

We continuously applied a MEDLINE (via Ovid SP) email alert service established by the Cochrane Metabolic and Endocrine Disorders (CMED) Group to identify newly published trials using the same search strategy as described for MEDLINE (for details

on search strategies, see Appendix 1). If we identified new trials for inclusion, we evaluated these, incorporated the findings into our review, and resubmitted another review draft (Beller 2013).
If we detected additional relevant key words during any of the electronic or other searches, we modified the electronic search strategies to incorporate these terms and documented the changes.

Searching other resources

We attempted to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses, and health technology assessment reports. We also contacted authors of included trials to identify any further trials that we may have missed.

Data collection and analysis

Selection of studies

Two review authors (two of KR, JC, EL, COM, LA, LAl-K, EM, LE) independently scanned the abstract, title, or both, of every record retrieved, to determine which trials we should assess further. We investigated all potentially relevant articles as full text. We resolved any discrepancies through consensus or through recourse to a third review author (KR, JC, EL, LAl-K). Where resolution of a disagreement was not possible, we added the article to those 'awaiting assessment' and contacted trial authors for clarification. We presented an adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart showing the process of trial selection (Liberati 2009).

Data extraction and management

For trials that fulfilled the inclusion criteria, two review authors (of JC, EL, COM, LA, EM, KR) independently abstracted key participant and intervention characteristics and reported data on efficacy outcomes and adverse events using standard data extraction templates as supplied by the CMED, with any disagreements to be resolved by discussion, or, if required, by consultation with a third review author (KR) (for details see Table 1; Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; Appendix 9) .
We provided information including trial identifier about potentially relevant ongoing trials in the Characteristics of ongoing studies table and in Appendix 5 (Matrix of study endpoints (publications and trial documents)). We attempted to find the protocol of each included trial and reported primary, secondary, and other outcomes in comparison with data in publications in Appendix 5.
We e-mailed all authors of included trials to enquire whether they were willing to answer questions regarding their trials. Appendix 10 shows the results of this survey. Thereafter, we sought relevant missing information on the trial from the primary author(s) of the article, if required.

Dealing with duplicate and companion publications

In the event of duplicate publications, companion documents, or multiple reports of a primary trial, we attempted to maximise yield of information by collating all available data and using the most complete data set aggregated across all known publications. If in doubt, we gave priority to the publication reporting the longest follow-up associated with our primary or secondary outcomes.

Assessment of risk of bias in included studies

Two review authors (of JC, EL, COM, LA, EM, KR) independently assessed the risk of bias of each included trial. We resolved any disagreements by consensus or by consulting a third review author (KR).
We used the Cochrane 'Risk of bias' assessment tool to evaluate the following criteria (Higgins 2011a; Higgins 2011b).

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Imbalances in baseline characteristics.
- Blinding of participants and personnel (performance bias).
- Blinding of outcome assessment (detection bias).
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Other potential sources of bias.

We judged the above 'Risk of bias' criteria as 'low risk', 'high risk', or 'unclear risk', and evaluated individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We presented a 'Risk of bias' graph and a 'Risk of bias' summary figure. We assessed the impact of individual bias domains on trial results at endpoint and trial levels. In case of high risk of selection bias, we marked all endpoints investigated in the associated trial as 'high risk'.
We evaluated whether imbalances in baseline characteristics existed and how these were addressed (Egbewale 2014).
For performance bias (blinding of participants and personnel) and detection bias (blinding of outcome assessors), we evaluated the risk of bias separately for each outcome type (objective and subjective) (Hróbjartsson 2013). We noted whether endpoints were self reported, investigator assessed, or adjudicated outcome measures.
We considered the implications of missing outcome data from individual participants per outcome such as high drop-out rates (for example above 15%) or disparate attrition rates (for example difference of 10% or more between trial arms).
We assessed outcome reporting bias by integrating the results of 'Examination of outcome reporting bias' (Kirkham 2010) (Appendix 6), in the 'Matrix of study endpoints (publications and trial documents)' (Appendix 5), and section 'Outcomes (outcomes reported in abstract of publication)' of the Characteristics

of included studies table. This analysis formed the basis for the judgement of selective reporting (reporting bias).
We distinguished between self reported, investigator assessed, and adjudicated outcome measures.
We defined the following endpoints as potentially self reported ('subjective') outcomes.

- Adverse events.
- Health-related quality of life.
- Parent-child relationship or assessment of parenting.
- Participant views of the intervention.

We defined the following outcomes as potentially investigator assessed ('objective') outcomes.

- Changes in BMI and body weight.
- Adverse events.
- All-cause mortality.
- Morbidity.

Measures of treatment effect

We expressed dichotomous data as odds ratios or risk ratios with 95% confidence intervals (CIs). We expressed continuous data as mean differences with 95% CI. We expressed time-to-event data as hazard ratios with 95% CIs.

Unit of analysis issues

We took into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials, and multiple observations for the same outcome.

Dealing with missing data

We obtained relevant missing data from authors, if feasible, and evaluated important numerical data such as screened, eligible, randomised participants as well as intention-to-treat, as-treated, and per-protocol populations. We investigated attrition rates, for example dropouts, losses to follow-up, and withdrawals, and critically appraised issues of missing data and imputation methods (for example last observation carried forward).
Where standard deviations for outcomes were not reported, and we did not receive information from trial authors, we calculated these following the methods presented in the *Cochrane Handbook for Systematic Reviews of Interventions*. Where papers did not report results as change from baseline, we calculated this and for the standard deviation differences followed the methods presented in the *Cochrane Handbook for Systematic Reviews of Interventions* for imputing these (Section 16.1.3.2 Imputing standard deviations for changes from baseline), and assumed a correlation of 0.5 between baseline and follow-up measures as suggested by Follmann 1992.

Assessment of heterogeneity

In the event of substantial clinical, methodological, or statistical heterogeneity, we did not report trial results as meta-analytically pooled effect estimates. We identified heterogeneity by visual inspection of the forest plots and by using a standard Chi² test with a significance level of $\alpha = 0.1$, in view of the low power of this test.
We examined heterogeneity using the I^2 statistic, which quantifies inconsistency across trials to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003), where an I^2 statistic of 75% or more indicates a considerable level of inconsistency (Higgins 2011a).
When we found heterogeneity, we attempted to determine potential reasons for it by examining individual trial and subgroup characteristics.

Assessment of reporting biases

If we had included 10 or more trials for a given outcome, we would have used funnel plots to assess small-trial effects. Given that there are several explanations for funnel plot asymmetry, we would have interpreted results carefully (Sterne 2011).

Data synthesis

Unless there was good evidence for homogeneous effects across trials, we primarily summarised data that was at low risk of bias by means of a random-effects model (Wood 2008). We had planned to interpret random-effects meta-analyses with due consideration of the whole distribution of effects, ideally by presenting a prediction interval, however relatively few trials were included in each category, of low methodological quality, and so we did not conduct these analyses (Higgins 2009). A prediction interval specifies a predicted range for the true treatment effect in an individual trial (Riley 2011). In addition, we performed statistical analyses according to the statistical guidelines referenced in the latest version of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Quality of evidence

We presented the overall quality of the evidence for each outcome according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which takes into account issues not only related to internal validity (risk of bias, inconsistency, imprecision, publication bias) but also to external validity such as directness of results. Two review authors (JC, EL) independently rated the quality of the evidence for each outcome. We presented a summary of the evidence in a 'Summary of findings' table, which provides key information about the best estimate of the magnitude of the effect, in relative terms and absolute differences for each relevant comparison of alternative management strategies, numbers of participants and trials addressing each important outcome, and the rating of the overall confidence in effect

estimates for each outcome. We created the 'Summary of findings' table based on the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We presented results for the outcomes as described in Types of outcome measures. In addition, we established an appendix 'Checklist to aid consistency and reproducibility of GRADE assessments' to help with standardisation of 'Summary of findings' tables (Appendix 9) (Meader 2014).

Subgroup analysis and investigation of heterogeneity

We expected the following characteristics to introduce clinical heterogeneity, and planned to carry out subgroup analyses with investigation of interactions where data permitted.

- Differences in BMI at baseline.
- Length of follow-up.
- The impact of comparator/control: whether concomitant therapy or no treatment (true control).
- The setting in which the intervention was conducted.

Sensitivity analysis

We planned to perform sensitivity analyses in order to explore the influence of the following factors (when applicable) on effect sizes by restricting analysis to the following.

- Published trials.
- Taking into account risk of bias, as specified in the Assessment of risk of bias in included studies section.
- Very long or large trials to establish the extent to which they dominate the results.
- Trials using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We also tested the robustness of the results by repeating the analysis using different statistical models (fixed-effect and random-effects models).

RESULTS

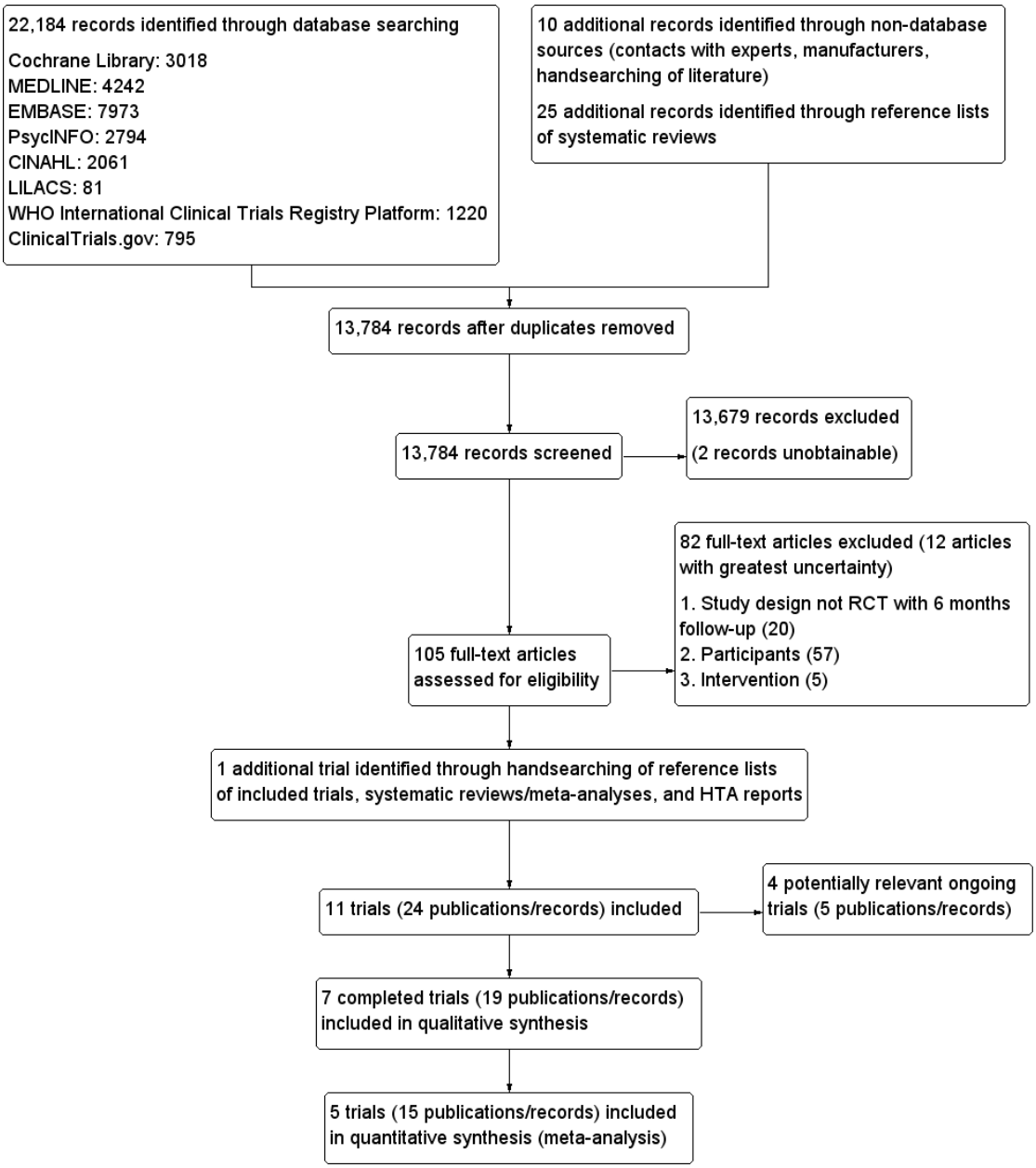
Description of studies

For a detailed description of trials, see the Characteristics of included studies, Characteristics of excluded studies, and Characteristics of ongoing studies sections.

Results of the search

The searches generated 13,784 hits after duplicates were removed. Screening of titles and abstracts identified 105 papers to evaluate for formal inclusion and exclusion. Seven completed randomised controlled trials (RCTs) fulfilled the inclusion criteria and were included in the review. For a detailed description of the included trials, see Characteristics of included studies. We also identified four ongoing trials; see Characteristics of ongoing studies. We have presented the flow of trials through the review in Figure 1.

Figure 1. Study flow diagram.



Included studies

For a detailed description of the characteristics of included trials, see Characteristics of included studies and Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; Appendix 11). The following is a succinct overview.

Source of data

We obtained the majority of data presented in the review from published literature, including supplementary published data and trials registers where available. For three trials, data were provided via correspondence with the trial authors (Appendix 10).

Comparisons

We identified two main comparisons: six trials compared multicomponent interventions versus control (Bocca 2012; Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014; Taveras 2011), and one trial compared dietary interventions versus control (Kelishadi 2009).

Overview of trial populations

The seven trials included a total of 923 participants, with over half of these from just one trial (Taveras 2011). In total, 529 participants were randomised to an intervention and 394 to a comparator. The proportion of participants finishing the trial was lowest in Bocca 2012 at three years' follow-up (39%), however data at this follow-up are not yet available for inclusion in the review. Similarly, two-year data (48% follow-up) are not yet available for Lanigan 2010. For follow-up reported in this review, the proportion of participants finishing the trial ranged from 47% to 93% in the intervention groups and 71% to 94% in the comparator groups. Individual sample size ranged between 18 and 475. See Table 1 for details.

Trial design

Six trials were parallel comparisons with individual randomisation. One trial was a cluster RCT (Taveras 2011), where the primary care practice was the unit of randomisation. All seven RCTs had a superiority design. Two RCTs had three comparisons (two intervention groups and one usual care or control arm) (Kelishadi 2009; Stark 2014); the remaining trials had two comparison groups. Five trials were single-centre trials (Bocca 2012; Kelishadi 2009; Lanigan 2010; Stark 2011; Stark 2014), one trial was conducted in four centres (Quattrin 2012), and the cluster RCT was undertaken in 10 centres (Taveras 2011).

Trials were performed from 2003 to 2013. The duration of the interventions was six months in four trials (Kelishadi 2009; Lanigan 2010; Stark 2011; Stark 2014), and ranged from 16 weeks, in Bocca 2012, to two years, in Taveras 2011. The duration of follow-up ranged from 12 months to three years. One trial terminated before regular end (after 105 families were recruited), as preliminary analysis indicated efficacy (Bocca 2012).

Settings

The interventions were carried out in an outpatient setting in three trials (Bocca 2012; Stark 2011; Stark 2014), primary care in two trials (Quattrin 2012; Taveras 2011), a community setting in one trial (Lanigan 2010), and an obesity research clinic in one trial (Kelishadi 2009). Four trials were conducted in the USA (Quattrin 2012; Stark 2011; Stark 2014; Taveras 2011), and one was conducted in each of the Netherlands (Bocca 2012), UK (Lanigan 2010), and Iran (Kelishadi 2009).

Participants

The diagnostic criteria for overweight and obesity differed between the trials. Two trials included children with BMI on or above the 85th percentile and who had a parent with BMI 27 or more, in Quattrin 2012, or BMI over 25, in Taveras 2011. The latter trial also included children with BMI on or above the 95th percentile and no overweight parent. Three other trials included children with BMI on or above the 95th percentile (Kelishadi 2009; Stark 2011; Stark 2014); two of these trials also specified BMI less than 100% above mean BMI and a parent with BMI 25 or more (Stark 2011; Stark 2014). Lanigan 2010 included children with BMI on or above the 91st percentile or whose weight had crossed centiles upwards, and Bocca 2012 included children who were 'overweight or obese' as defined by the International Obesity Task Force.

The age range for trial eligibility was 1 to 5 years (Lanigan 2010), 2 to 5 years (Quattrin 2012; Stark 2011; Stark 2014), 3 to 5 years (Bocca 2012), and 2 to 6.9 years (Taveras 2011). Kelishadi 2009 did not specify an age range. The mean age of children included in the trials ranged from 4 to under 6 years in six of the seven trials, and was 2.5 years in Lanigan 2010. The proportion of girls varied from 25% to 80%, but was not reported by one trial (Kelishadi 2009). Five trials reported mean BMI (Bocca 2012; Kelishadi 2009; Lanigan 2010; Quattrin 2012; Taveras 2011), which ranged from 18 to 22.7, and five trials reported BMI z score (Bocca 2012; Lanigan 2010; Quattrin 2012; Stark 2014; Taveras 2011), which ranged from 1.0 to 2.7. Stark 2011 reported mean BMI percentile (98 to 99). Mean parental BMI was 36 to 37 in the one trial reporting this (Quattrin 2012). Taveras 2011 reported the proportions of parents with BMI less than 25 (3% to 5%), 25 to 30 (36% to 52%), and 30 or more (44% to 61%).

Five of the seven trials reported ethnicity. The proportion of participants categorised as white was over 70% in four of the trials (Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014), and 47% to 70% in the fifth trial (Taveras 2011). Five trials reported socioeconomic status using different indicators (Hollingshead score, Hollingshead classification, family income, non-manual social class, or parental educational attainment) (Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014; Taveras 2011).

Interventions

The interventions in six of the seven trials included a combination of nutritional, physical activity, and behavioural components, although approaches differed between the trials (Bocca 2012; Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014; Taveras 2011). See Characteristics of included studies and Appendix 2 for details of each trial. Two trials reported the same intervention, 'Learning about Activity and Understanding Nutrition for Child Health' (LAUNCH), which involved 18 group-based clinic sessions and individual home visits over six months, targeting lifestyle behaviour modification and parenting skills (Stark 2011; Stark 2014). Stark 2014 also compared a less intensive mode of delivery, which was identical to the former except that individual home visits were not undertaken. Quattrin 2012 reported a family-based parenting and behavioural intervention involving 13 group sessions over 12 months, individual meetings to shape goals, and 10 phone calls in between sessions. Bocca 2012 assessed a multidisciplinary intervention involving dietary advice, physical activity sessions, and psychological counselling for parents, with a total of 25 sessions over 16 weeks. Taveras 2011 reported 'High Five for Kids', a behavioural intervention using motivational interviewing face-to-face and by telephone, educational modules, and behavioural goal setting. The intensive phase of the intervention lasted for 12 months followed by a 12-month maintenance phase, although no details were reported of this. Lanigan 2010 assessed the 'Trim Tots' healthy lifestyle programme, which included nutritional education, physical activity, and behavioural change components. Sessions were delivered in the community twice weekly for three months, then weekly for three months.

The comparators in these six trials were enhanced usual care (Stark 2011; Stark 2014), information control (Quattrin 2012), usual care (Bocca 2012; Taveras 2011), or a wait-list control (Lanigan 2010), with differences between trials in the intensity and amount of contact (Characteristics of included studies; Appendix 2).

One trial compared two dietary approaches (dairy rich and energy restricted) plus healthy lifestyle education versus healthy lifestyle education alone (Kelishadi 2009). The family-centred education sessions focused on health, nutrition, and physical activity and occurred monthly over six months in all three groups.

Outcomes

Six of seven trials explicitly stated a primary/secondary endpoint in the publication (Appendix 5). The most commonly defined primary outcome in the publications was a BMI variable: BMI z score (Bocca 2012; Lanigan 2010; Stark 2011; Stark 2014), BMI (Taveras 2011), or percent BMI overweight (Quattrin 2012). Where reported, primary outcomes defined in publications reflected those defined in trial registers, although in three trial publications (Bocca 2012; Stark 2011; Stark 2014), a greater number of outcomes were specified as primary. In Lanigan 2010, the primary outcome was specified as BMI in the trial register and BMI z score in the publication. Only one of seven trials reported on adverse events (Lanigan 2010), two reported health-related quality of life (Bocca 2012; Stark 2011), five reported behaviour change (Bocca 2012; Kelishadi 2009; Stark 2011; Stark 2014; Taveras 2011), two reported participant views of the intervention (Stark 2011; Taveras 2011), and two reported parent-child relationship or assessment of parenting (Stark 2011; Stark 2014). No trials investigated all-cause mortality, morbidity, or socioeconomic effects. All seven trials provided a definition of endpoint measurement for BMI (Appendix 7). One trial was published as an abstract only, and a number of secondary outcomes are not yet available (Lanigan 2010).

Excluded studies

After evaluation of the full publication, we excluded 82 of 105 full-text articles. The main reasons for exclusion were the types of participants included and the trial design not being an RCT with at least six months' duration. Many trials had multiple reasons for exclusion (for further details see Characteristics of excluded studies, which lists the 12 trials with the most uncertainty regarding inclusion).

Risk of bias in included studies

For details on risk of bias of included trials, see Characteristics of included studies. For an overview of review authors' judgements about each 'Risk of bias' item for individual trials and across all trials, see Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included trials (blank cells indicate that the particular outcome was not investigated in some trials).

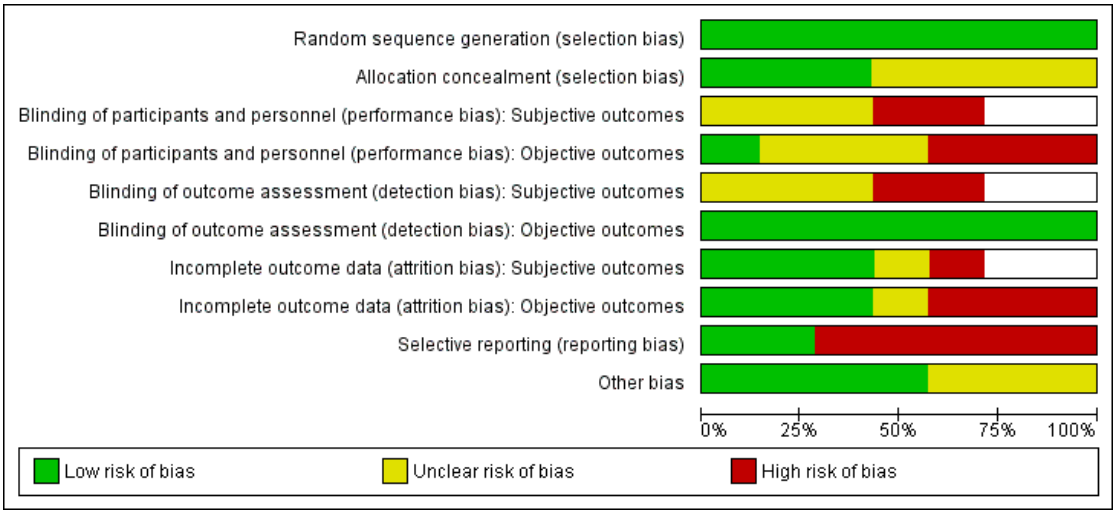
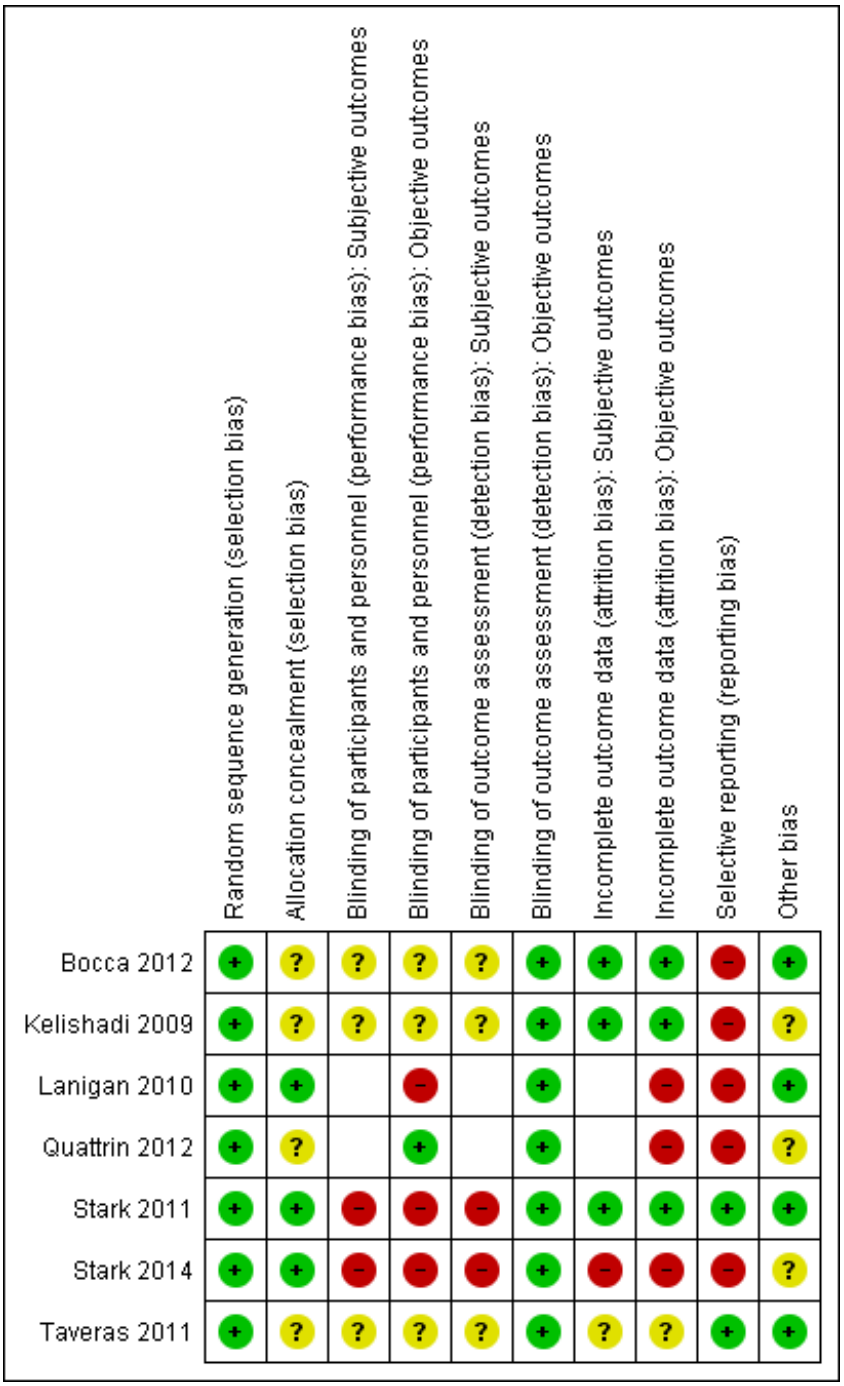


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study (blank cells indicate that the study did not report that particular outcome).



Allocation

All seven trials reported adequate sequence generation, but only three described allocation concealment (Lanigan 2010; Stark 2011; Stark 2014). The risk of selection bias is therefore uncertain in four of the seven included trials.

Blinding

We judged only one trial to have a low risk of performance bias, as participants and personnel were blinded to treatment allocation (Quattrin 2012). Three trials did not undertake blinding of participants and personnel (Lanigan 2010; Stark 2011; Stark 2014); we judged these trials to have a high risk of performance bias for both objective and subjective outcomes (where reported). The risk of performance bias was unclear in three trials: one was described as single blind (Bocca 2012), and another as double-blind (in the trial record only), but it was unclear who was blinded and how this was achieved (Taveras 2011), and in the third blinding was not reported (Kelishadi 2009).

We judged the risk of detection bias to be low for objective outcomes in all trials, regardless of whether or not outcome assessors were blinded. Two trials reporting subjective outcomes did not undertake blinding of outcome assessors (Stark 2011; Stark 2014); we judged these trials to have a high risk of detection bias for subjective outcomes. The risk of detection bias for subjective outcomes was unclear in three trials, either because blinding was not reported or it was unclear who was blinded and how this was achieved (Bocca 2012; Kelishadi 2009; Taveras 2011).

Incomplete outcome data

We judged the risk of attrition bias to be low in three trials (Bocca 2012; Kelishadi 2009; Stark 2011). Three trials had an imbalance in attrition between groups and were judged to have a high risk of attrition bias (Lanigan 2010; Quattrin 2012; Stark 2014). The risk of attrition bias was unclear for one trial that did not report reasons for attrition and only reported baseline and results data for participants completing the trial (Taveras 2011).

Selective reporting

We judged only two trials to have a low risk of selective reporting bias (Stark 2011; Taveras 2011). We judged the remaining five trials to have a high risk of selection bias, due to some outcomes being incompletely reported or not reported at all.

Other potential sources of bias

There was a low risk of bias from other sources in four trials (Bocca 2012; Lanigan 2010; Stark 2011; Taveras 2011). We judged the risk of bias from other sources to be unclear in the remaining three trials.

Effects of interventions

See: **Summary of findings for the main comparison**; **Summary of findings 2**

Multicomponent interventions versus control

Six trials compared multicomponent interventions with usual care, enhanced usual care, information control, or wait-list control. One trial assessed two interventions, LAUNCH with home visits and LAUNCH without home visits (described in the analyses as LAUNCH clinic only) (Stark 2014). Stark 2011 also assessed LAUNCH (with home visits). The other four trials each assessed different multicomponent interventions (Bocca 2012; Lanigan 2010; Quattrin 2012; Taveras 2011).

We considered outcomes here at the end of the intervention (if six months or longer) and at any follow-up period. The intervention period was six months in three trials (Lanigan 2010; Stark 2011; Stark 2014), and 12 months in two trials (Quattrin 2012; Taveras 2011). The intervention was 16 weeks in one trial (Bocca 2012); we did not include outcomes at this time point in this review. Four trials reported outcomes at 12 months, in Bocca 2012, Stark 2011 and Stark 2014, or 18 months, in Quattrin 2012, from baseline (six to eight months from end of intervention), and one trial, Quattrin 2012, reported outcomes at 24 months (12 months from end of intervention). Lanigan 2010 followed participants for 24 months, but data are not yet available. Bocca 2012 followed participants for 36 months, but data at this time point were not reported in a useable format.

The proportion of participants finishing the trial (or the longest reported follow-up, if different) was less than 80% in four trials, Bocca 2012, Lanigan 2010, Quattrin 2012, Stark 2014, out of the six (Table 1), moreover there was a differential rate of losses to follow-up between groups in three of these trials (Lanigan 2010; Quattrin 2012; Stark 2014). Attrition was highest in the multicomponent intervention arms of Lanigan 2010 and Quattrin 2012, and the LAUNCH home visits arm of Stark 2014 (although both intervention arms had higher attrition than the enhanced usual care arm in this trial).

Primary outcomes

Changes in body mass index (BMI) and body weight

All six trials reported BMI z score (Bocca 2012; Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014; Taveras 2011). Pooling the

studies in a random-effects meta-analyses (Analysis 1.1) demonstrated a reduction in BMI z score in the intervention groups compared with controls at the end of intervention: mean difference (MD) -0.26 units (95% confidence interval (CI) -0.37 to -0.16); P < 0.00001; 210 participants; 4 trials; low-quality evidence). At 12 to 18 months' follow-up, the MD was -0.38 units (95% CI -0.58 to -0.19); P = 0.0001; 202 participants; 4 trials; low-quality evidence). One trial, Quattrin 2012, reported outcomes at 24 months' follow-up (12 months' postintervention) and found the benefit was maintained (MD -0.25 units (95% CI -0.40 to -0.10)). One cluster RCT comparing intervention with control reported a change in BMI z score from baseline to one year of 0.05 units (95% CI -0.14 to 0.04); P = 0.28 (Taveras 2011).

Three trials reported BMI at the end of intervention or postintervention: Lanigan 2010 showed a MD of -0.40 kg/m² (95% CI -0.85 to 0.05) in 64 participants, and the cluster RCT by Taveras 2011 an adjusted (child age, sex, ethnicity, parent education, overweight/obesity status at baseline, household income, time elapsed from baseline to follow-up) MD of -0.21 kg/m² (95% CI -0.50 to 0.07) in 445 participants. Eight months' postintervention, Bocca 2012 reported a MD of -1.00 kg/m² (95% CI -1.79 to -0.21) in 57 participants (Analysis 1.2).

Three of the trials reporting BMI z score also reported additional BMI variables, including changes in percent over BMI (Analysis 1.3) and BMI percentile (Analysis 1.4), which reflected the results in BMI z score.

Five trials reported change in body weight (Bocca 2012; Lanigan 2010; Quattrin 2012; Stark 2011; Stark 2014) (Analysis 1.5). Pooling the trials in a random-effects meta-analysis showed less weight gain with the interventions compared with control at the end of the intervention: MD -1.18 kg (95% CI -1.91 to -0.45); P = 0.001; 210 participants; 4 trials; low-quality evidence) and at 12 to 18 months' follow-up: MD -2.81 kg (95% CI -4.39 to -1.22); P = 0.0005; 202 participants; 4 trials; low-quality evidence).

One trial, Quattrin 2012, reported change in body weight at 24 months' follow-up (12 months' postintervention) and found the benefit was maintained: MD -1.60 kg (95% CI -2.42 to -0.78); 96 participants). Follow-up was low (58%) in the intervention arm of this trial.

Three trials reported change in parental BMI or weight (Quattrin 2012; Stark 2011; Stark 2014); these trials required the parent to have a BMI of least 25 or 27 for trial inclusion. Pooling the trials in a meta-analysis demonstrated a reduction in parental BMI in the intervention group compared with controls at the end of intervention (6 or 12 months) (MD -2.00 kg/m² (95% CI -2.52 to -1.48); P < 0.00001; 113 participants; 2 trials; low-quality evidence) and at 12 to 18 months' follow-up (MD -2.08 kg/m² (95% CI -2.65 to -1.51); P < 0.00001; 112 participants; 2 trials; low-quality evidence). Quattrin 2012 also reported outcomes at 24 months' follow-up, where the effect remained stable (MD -2.00 kg/m² (95% CI -2.57 to -1.43); 96 participants) (Analysis 1.6).

The effect on parental body weight was similar (Analysis 1.7), with parents in the intervention group reducing weight by around 5 kg more than the control group at the end of the intervention (MD -4.69 kg (95% CI -7.27 to -2.11); P = 0.0004; 146 participants; 3 trials; low-quality evidence) and at 12 to 18 months' follow-up (MD -5.14 kg (95% CI -8.96 to -1.33); P = 0.008; 49 participants; 2 trials; low-quality evidence). Only one trial reported outcomes at 24 months' follow-up (Quattrin 2012), where the effects remained (MD -6.70 kg (95% CI -8.42 to -4.98)).

Adverse events

Only one trial reported, as an abstract only, on adverse events (Lanigan 2010), stating that no adverse events were observed (Appendix 8). Further details, such as how adverse events were monitored, were not provided.

Secondary outcomes

Health-related quality of life and self esteem

Three trials reported health-related quality of life (Bocca 2012; Stark 2011; Stark 2014), but measures and scores used varied between trials (Appendix 11). Bocca 2012 reported two tools, the Dutch Child AZL TNO Quality-of-Life (DUX-25), which measures daily activities, and the Dutch edition of the Child Health Questionnaire Parent Form (CHQ-PF50), which measures health perception. At 12 months' follow-up (eight months postintervention), a statistically significant higher increase was found in 40 participants in the multidisciplinary intervention group compared with the usual care group in the DUX-25 total score (change in median of the total score: +5 in the intervention group versus -5 in the control group; 0 to 100 scale with higher scores indicating better health-related quality of life) and in one of four domains (physical score; change in median: +8 in the intervention group versus -4 in the control group; with higher scores indicating better health-related quality of life), but no substantial differences were found in any of the 15 items on the CHQ-PF50 (Analysis 1.8; Analysis 1.9). Parents of 50% to 57% of randomised children completed questionnaires.

Stark 2011 reported the Pediatric Quality of Life Inventory (PedsQL) Generic Core scales, using the total score and the physical functioning, emotional functioning, and social functioning subscales, however only data for physical functioning were reported. A statistically significant improvement (higher scores indicate better quality of life) in the change in health-related quality of life in physical functioning was found at the end of intervention (six months, mean +9.5 units in the intervention group versus -1.7 units in the control group) and at 12 months' follow-up (mean

+13.8 units in the intervention group versus -2.7 units in the control group) (Analysis 1.10).
Stark 2014 used the parent version of the PedsQL (total score) and found no substantial differences between multicomponent interventions and control in the total score (Analysis 1.11).
No trials measured self esteem.

All-cause mortality

Not reported.

Morbidity

Not reported.

Anthropometric measures other than BMI

One trial reported waist circumference at the end of the six-month intervention (Lanigan 2010) (Analysis 1.12), and one trial reported a number of anthropometric measures at 12 months' follow-up (eight months after intervention end) (Bocca 2012), including waist circumference (Analysis 1.12), waist circumference z score (Analysis 1.13), hip circumference (Analysis 1.14), hip circumference z score (Analysis 1.15), upper arm circumference (Analysis 1.16), per cent body fat (Analysis 1.17), fat-free mass (Analysis 1.18), visceral fat (Analysis 1.19), and subcutaneous fat (Analysis 1.20). Although these outcomes tended to favour the intervention, differences were only statistically significant for upper arm circumference and visceral fat. Caution is required in the interpretation of these results due to the number of outcomes measured.

Behaviour change

Four trials reported some form of assessment of behaviour change (Bocca 2012; Stark 2011; Stark 2014; Taveras 2011).
Four trials measured physical activity, however different methods and outcomes were used (Appendix 7). Taveras 2011 found no substantial difference in change in number of hours per day of outdoor active playtime at the end of intervention (Analysis 1.21), and Bocca 2012 found no substantial difference in change in number of steps per day at 12 months' follow-up (Analysis 1.22) Of the two trials evaluating LAUNCH (Stark 2011; Stark 2014), both reported change in average daily minutes of moderate and vigorous physical activity (Analysis 1.23; Analysis 1.24). Stark 2011 found no substantial difference in physical activity, and although data from Stark 2014 suggest a statistically significant effect in the LAUNCH clinic only group compared with control at 12 months' follow-up, this result should be viewed with caution as the treatment effect was not statistically significant when computed using maximum likelihood estimation to account for missing data by Stark 2014.
One cluster RCT, Taveras 2011, reported a greater reduction in the number of servings per day of sugar-sweetened drinks (MD -0.26 (95% CI -0.49 to -0.03); Analysis 1.25), but this was not statistically significant in an adjusted analysis (MD -0.22 (95% CI -0.52 to 0.08)). Similarly, there was no substantial difference in the increase in servings per day of fruits and vegetables (MD 0.06 (95% CI -0.21 to 0.33); Analysis 1.26), adjusted analysis: MD 0.12 (95% CI -0.17 to 0.42). However, we found a statistically significant difference in the reduction in hours per day of television and video viewing: MD -0.46 hrs (95% CI -0.70 to -0.22); Analysis 1.27), adjusted analysis: MD -0.36 hrs (95% CI -0.64 to -0.09). Analyses were adjusted for child age, sex, and race/ethnicity; parent education and overweight/obesity status at baseline; household income; and exact time elapsed from baseline to follow-up visit.

Participant views of the intervention

Two trials reported the participants' views of the interventions. Taveras 2011 reported that 97% were "somewhat" or "very satisfied" with the High Five for Kids program, and that 91% would recommend the program to their family and friends. Using the Barrier to Treatment Participation Scale questionnaire, Stark 2011 reported no statistically significant difference between LAUNCH and comparator (paediatric counselling) on parent perceptions of treatment demands (11 for both groups) or relevance of treatment (11.3 versus 10.6, respectively). Parents in LAUNCH reported significantly greater stressors and obstacles compared to parents in the comparator group (33 ± 8.2 versus 25.6 ± 4.7, P = 0.038). Parents in LAUNCH and comparator were highly satisfied with treatment and did not differ substantially in their satisfaction ratings for information on nutrition (4.86 ± .38 versus 4.30 ± 1.25, P > 0.05) or physical activity (4.71 ± .49 versus 4.00 ± 1.25, P > 0.05), or in their satisfaction with ability to make recommended changes (4.26 ± .49 versus 4.20 ± 1.23, P > 0.05).

Parent-child relationship or assessment of parenting

Two trials reported the Child Feeding Questionnaire (CFQ), a self report measure to assess parental beliefs, attitudes, and practices regarding child feeding (Stark 2011; Stark 2014) (Appendix 7). However, the trial authors report limited data. The CFQ contains 31 items, loading on seven factors. Four items relate to parental perception of child and parent weight, and concern about weight, which may elicit parental control in feeding. Pressure to eat scores were reduced by 0.9 and 0.6 at six months and by 0.6 and 0.3 at 12 months in the intervention and control groups, respectively (Stark 2011). Restriction to eat was described as "stable at approximately 4" with no statistically significant differences. Stark 2014 state "from baseline to months 6 and 12, CFQ restriction and pressure to eat remained relatively low (< 2.3) across all time points with no significant changes between groups".

Socioeconomic effects

No trials reported socioeconomic effects.

Diet interventions versus control

One three-arm trial compared two diets (dairy rich and energy restricted) plus healthy lifestyle education with health lifestyle education alone (Kelishadi 2009). The intervention was of six months' duration, and follow-up was three years from baseline, with 90.1%, 77.5%, and 90% follow-up in the dairy-rich, energy-restricted, and control groups, respectively. We judged the trial to have a high risk of selective outcome bias and an unclear risk of selection bias, performance bias, detection bias, and other bias. The reported standard deviations appear very small and could possibly be standard errors.

Primary outcomes

Changes in body mass index (BMI) and body weight

For change in BMI z score, see Analysis 2.1. At the end of the intervention, BMI z score was reduced in all groups, however the reduction was greater with both the dairy-rich diet (MD -0.10 units (95% CI -0.11 to -0.09)) and energy-restricted diet (MD units -0.10 (95% CI -0.11 to -0.09)) than with control. At 12, 24, and 36 months' follow-up, the difference between the dairy-rich diet and control increased (MD units -0.20 (95% CI -0.21 to -0.19); MD -0.60 units (95% CI -0.61 to -0.59); MD -0.70 units (95% CI -0.71 to -0.69), respectively). In contrast, at 12 months' follow-up, the MD between the energy-restricted diet and control was 0.00 units (95% CI -0.01 to 0.01), and at 24 and 36 months' follow-up, the outcome favoured control (MD 0.10 units (95% CI 0.09 to 0.11); MD units 0.10 (95% CI 0.09 to 0.11), respectively).

Adverse events

Adverse events were not reported.

Secondary outcomes

Health-related quality of life and self esteem

Not reported.

All-cause mortality

Not reported.

Morbidity

Not reported.

Anthropometric measures other than BMI

Reductions in waist circumference were greater with both the dairy-rich (MD -0.30 cm (95% CI -0.39 to -0.21)) and energy-restricted diet (MD -0.80 cm (95% CI -0.91 to -0.69)) at the end of the intervention (Analysis 2.2). At three years' follow-up, only the dairy-rich diet remained better on waist circumference than control (MD -0.70 cm (95% CI -0.84 to -0.56)), while the energy-restricted diet had a worse outcome than the control group (MD 0.40 cm (95% CI 0.23 to 0.57)).

The dairy-rich diet group had a greater reduction in percentage body fat than control at the end of the intervention (MD -2.00% (95% CI -2.18 to -1.82)), but this was not maintained at 24 months' follow-up (Analysis 2.3). There were no substantial differences in percentage body fat between the energy-restricted diet and control at either time point. Data at three years' follow-up were not reported for this outcome.

Behaviour change

Kelishadi 2009 stated that "mean daily energy expenditure did not differ significantly by group at each time period throughout the study", however data were presented in a figure only and could not be accurately estimated by review authors.

Participant views of the intervention

Participant views were not reported.

Parent-child relationship or assessment of parenting

Not reported.

Socioeconomic effects

Socioeconomic effects were not reported.

Subgroup analyses

We did not perform subgroups analyses because there were not enough trials to estimate effects in various subgroups.

Sensitivity analyses

We did not perform any sensitivity analyses because there were not enough trials included in the analyses.

Assessment of reporting bias

We did not draw funnel plots due to limited number of trials per outcome (n = 7).

Ongoing studies

We found four ongoing RCTs. All are parallel RCTs, with estimated sample sizes of 28 to 240. For descriptions of the interventions, see Characteristics of ongoing studies; one trial focuses on parenting and parent lifestyle, and the other three trials are multicomponent interventions. The primary outcome includes BMI z score or BMI in all trials. The trial completion date ranges from November 2015 to August 2016, where reported.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children aged 0 to 6 years

Patient or population: preschool children (aged 0 to 6 years) with overweight or obesity
Settings: obesity research clinic
Intervention: dietary interventions + healthy lifestyle education
Comparison: healthy lifestyle education

Outcomes	Healthy lifestyle education	Dietary intervention + healthy lifestyle education	Relative effect (95% CI)	No of participants (trials)	Quality of the evidence (GRADE)	Comments
Changes in BMI and body weight **1. Dairy-rich diet** **a. BMI z score [units]**[a] Follow-up: 6 months **b. BMI z score [units]** Follow-up: 36 months **2. Energy-restricted diet** **a. BMI z score [units]** Follow-up: 6 months **b. BMI z score [kg/m²]** Follow-up: 36 months	**1. Dairy-rich diet** a. The mean change in BMI z score was -0.5 units in the control group b. The mean change in BMI z score was +0.6 units in the control group **2. Energy-restricted diet** a. The mean change in BMI z score was -0.5 units in the control group b. The mean change in BMI z score was +0.6 units in the control group	**1. Dairy-rich diet** a. The mean change in BMI z score in the intervention group was **0.1 units lower (0.11 lower to 0.09 lower)** b. The mean change in BMI z score in the intervention group was **0.7 units lower (0.71 lower to 0.69 lower)** **2. Energy-restricted diet** a. The mean change in BMI z score in the intervention group was **0.1 units lower (0.11 lower to 0.09 lower)** b. The mean change in BMI z score in the intervention group was **0.1 units higher (0.09 higher to 0.11 higher)**	-	**1. Dairy-rich diet** a. 59 (1) b. 52 (1) **2. Energy-restricted diet** a. 57 (1) b. 47 (1)	**1. Dairy-rich diet** a/b ⊕◯◯◯ **very low**[b] **2. Energy-restricted diet** a/b ⊕◯◯◯ **very low**[b]	Lower units indicate more weight loss 2 dietary interventions and 1 control compared in one 3-arm randomised controlled trial (the number of participants in the control group was halved for the analysis and is shown here)
Adverse events	See comment	See comment	See comment	See comment	See comment	Not reported

Health-related quality of life and self esteem	See comment	See comment	See comment	See comment	See comment	Not reported
All-cause mortality	See comment	See comment	See comment	See comment	See comment	Not reported
Morbidity	See comment	See comment	See comment	See comment	See comment	Not reported
Parent-child relationship or assessment of parenting	See comment	See comment	See comment	See comment	See comment	No trials reported parent-child relationship or assessment of parenting
Socioeconomic effects	See comment	See comment	See comment	See comment	See comment	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
BMI: body mass index;**CI:** confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[a] "A BMI z score or standard deviation score indicates how many units (of the standard deviation) a child's BMI is above or below the average BMI value for their age group and sex. For instance, a z score of 1.5 indicates that a child is 1.5 standard deviations above the average value, and a z score of -1.5 indicates a child is 1.5 standard deviations below the average value' ' (NOO NHS 2011).
[b] Downgraded by three levels because of reporting bias, indirectness, and imprecision (one trial only with small number of participants); see Appendix 9.

DISCUSSION

Summary of main results

This systematic review summarised seven RCTs examining the effect of diet, physical activity, and behavioural interventions for treating overweight and obesity in preschool children up to the age of 6 years. We only included trials with at least a six-month outcome assessment, with the aim of assessing the longer-term effects of these interventions. Interventions and comparators varied between the included trials, and we divided the trials into two main groups to ease interpretation: multicomponent interventions and diet-only interventions. Outcomes assessed also varied between trials; the most commonly reported measure was BMI z score, but one trial reported BMI only. To allow comparison across trials, we analysed outcome data at the end of the intervention (whether this was 6 or 12 months) and at each reported follow-up period. Four trials had an unclear risk of selection bias, and most had an unclear or high risk of performance bias. All but two trials had a high risk of selective reporting bias.

Overall, multicomponent interventions were more successful than the comparators in reducing BMI and body weight in preschool children and their parents, and the effects were maintained two years after the start of the intervention. Improvements were found in some, but not all, aspects of health-related quality of life. The trials measured behaviour change inconsistently, and the effects of the interventions were more equivocal. There was limited assessment of participant views, parent-child relationship, or assessment of parenting; where these were reported, there was no difference between groups. Only one trial commented on adverse events, stating that none were reported.

One three-arm trial found that both the dairy-rich and energy-restricted dietary interventions resulted in greater reduction in BMI than the comparator at the end of the intervention period, but only the dairy-rich diet maintained this at 12 to 36 months' follow-up. Limited assessment was made of behaviour change; mean daily energy expenditure did not differ substantially between groups. Health-related quality of life, adverse effects, participant views, and parenting were not measured.

A number of outcomes such as all-cause mortality, morbidity, self esteem, and socioeconomic effects were not measured by any of the included trials.

Overall completeness and applicability of evidence

This review identified just seven trials assessing the effects of diet, physical activity, and behavioural interventions at six months or longer.

Six trials included multicomponent interventions. One of these trials had not yet fully reported at the time of writing, but will be included in the next review update. The duration of the interventions and length of follow-up varied slightly between these trials, with most reporting outcomes at 12 to 18 months' follow-up. Only one trial reported outcomes at two years' follow-up. Long-term effects of the interventions therefore remain uncertain.

One trial included two different diet interventions. The dairy-rich diet was high in curd and dough, which are traditional dairy products prepared and consumed in Iran, and may not be relevant to other countries. The benefits of the dairy-rich diet found in this trial would need to be confirmed in other trials.

Few of the trials reported secondary outcomes of interest to the review, and where these were reported there was little agreement in the types of measures used, making comparison difficult.

Results to date indicate that the magnitude of change in BMI z score with multicomponent interventions is likely to be clinically significant at all follow-up periods. Available data in adolescents show that a change of 0.25 or more is associated with improvements in adiposity and metabolic health, with larger changes eliciting greater benefits (Ford 2010). Though the populations are not directly comparable, this nevertheless gives some indication of clinical relevance.

Quality of the evidence

Overall, the quality of the evidence was low, with six of seven included trials judged to have a high risk of bias on individual 'Risk of bias' criteria, and only three trials having a low risk of selection bias. GRADE assessments of the outcomes in this review led to trials being downgraded for risk of bias and also imprecision owing to the small number of trials and small sample sizes. This makes overall interpretation of the data difficult.

Potential biases in the review process

We carried out a comprehensive search across major databases for interventions for childhood overweight and obesity for this review. In addition, we screened the reference lists of systematic reviews. Each included trial in the review was comprehensively selected, assessed, data extracted, and quality assessed by two review authors to minimise potential biases in the review process. We made no decisions about the analysis or investigation of heterogeneity after seeing the data. There were differences between the trials in both the interventions delivered and the comparators. We divided the comparisons in this review into two groups, multicomponent interventions and dietary interventions, in order to improve comparability of trials within groups. We made this decision after examination of trial characteristics of included trials, but before we viewed the data. Where relevant data were missing, either to allow assessment of eligibility or at the data extraction stage, the review authors contacted the trial authors for further information.

Agreements and disagreements with other studies or reviews

Previous systematic reviews identified an absence of RCTs assessing interventions for treating overweight or obesity in preschool-aged children (Bluford 2007; Bond 2009; Bond 2011; Oude Luttikhuis 2009). Since these reviews were undertaken, seven trials have been published and four trials are still ongoing. The current review is the first to synthesise the most up-to-date and highest-quality research available on the effectiveness of interventions for treating overweight or obesity in preschool-aged children.

The role of dietary interventions is more equivocal, with one trial suggesting that dairy interventions may be effective in the longer term, but not energy-restricted diets. Again, this trial had a high risk of bias.

Implications for research

The systematic review identified four ongoing trials of multicomponent interventions, which will contribute data to the results of an updated review. These trials will improve the robustness of the results for multicomponent interventions. Further research is required to determine whether the interventions have any adverse effects. Further research is also needed into the effects of different diet-only interventions.

AUTHORS' CONCLUSIONS

Implications for practice

Multicomponent interventions appear to be an effective treatment option for overweight or obese preschool children up to the age of 6 years. However, the current evidence is limited, and the trials had a high risk of bias. Most of the trials did not measure adverse events.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[author-defined order]*

Stark 2014

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1:1 **Superiority design**
Participants	**Inclusion criteria**: age 2 to 5 years; ≥ 95th percentile BMI but < 100% above the mean BMI; 1 parent with a BMI ≥ 25; medical clearance from paediatrician **Exclusion criteria**: non-English speaking; living ≥ 50 miles from the medical centre; disability or illness that would interfere with moderate physical activity; medical condition/medication associated with weight gain; enrolled in a weight control program **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 1 **Treatment before study**: - **Description of the interventions** (**L**earning about **A**ctivity and **U**nderstanding **N**utrition for **C**hild **H**ealth (LAUNCH): **LAUNCH home visits**: 18-session manualised, aim for small decreases or stabilise the rate of weight gain, consistent with current recommendations (reference given). 2 phases to the 6-month intervention: (1) Intensive intervention, 12 weekly 90-minute sessions, alternating between group-based clinic sessions (parent and child concurrent groups) , and individual home visits, targeted lifestyle behaviour modification and improving parenting skills. Parent sessions: psychologist led, education on diet (Weeks 2 to 7) , physical activity (Weeks 8 to 12), and parenting skills, provided with vegetables at each session for daily taste tests (14 days) between sessions. Child groups, paediatric psychologist and research coordinator, topics paralleled the parent group and focused on education about healthy eating, opportunities to try new foods and engage in physical activity. Home sessions (60 to 90 minutes) to support generalisation of clinic-taught skills to the home environment including a "home clean-out" where high-calorie, low-nutrient foods and beverages were either removed or a plan for eating them in moderation agreed; (2) Maintenance, 12 weeks of every-other-week sessions, alternating between group clinic, and individual home sessions, long-term planning, problem-solving around individual barriers, and use of parenting skills **LAUNCH clinic visits**: identical to LAUNCH home except home visits, instead parents were provided a "home clean-out" box to use on their own to eliminate high-calorie, low-nutrient foods from the home. **Enhanced standard of care**: paediatrician led, manualised, based on dietary and physical activity recommendations from American Academy of Pediatrics. One 45-min visit to explain BMI, BMI percentiles, and to review the child's growth chart. Modelled on published recommendations for screen time ≤ 2 h daily; active play ≥ 60 min daily; eliminating soda and ≤ 4 ounces juice daily; fruits and vegetables ≥ 5 servings daily; limiting eating out; appropriate portion sizes for preschoolers. Given a 1-page healthy food and activity brochure created by the Collaboration for Healthy Ohio. All were reimbursed USD 50 for completing each assessment
Outcomes	**Outcomes reported in abstract of publication**: change in BMI z score

Study details	**Run-in period**: none **Study terminated before regular end:** no **Study identifier**: NCT01419951
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	**Quote from publication:** "Tested two family-based behavioral treatments for obesity in preschool children, one meeting the Expert Committee guidelines for Stage 3 obesity intervention criteria (LAUNCH-clinic) and one exceeding Stage 3 (LAUNCH with home visit [LAUNCH-HV]), compared with a Stage 1 intervention, pediatrician counseling (PC)"
Notes	Pilot study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "Randomization was conducted using a random numbers table and was concealed until all baseline assessments were completed." **Comment**: information provided by author: used sequentially numbered, opaque, sealed envelopes. Appropriate
Allocation concealment (selection bias)	Low risk	**Quote from publication**: "Randomization was conducted using a random numbers table and was concealed until all baseline assessments were completed." **Comment**: information provided by author: used sequentially numbered, opaque, sealed envelopes. Appropriate
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	**Quote from publication**: "Randomization … was concealed until all baseline assessments were completed" **Comment**: self reported outcome measurement. Participants and personal not blind
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	**Quote from publication**: "Randomization … was concealed until all baseline assessments were completed" **Comment**: investigator assessed

Stark 2014 (*Continued*)

Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	**Quote from publication**: "Randomization … was concealed until all baseline assessments were completed" **Comment**: self reported outcome measurement. Participants and personal not blind
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Quote from publication**: "trained personnel … were unaware of the child's treatment assignment ..." **Comment**: investigator assessed, blinded outcome assessors
Incomplete outcome data (attrition bias) Subjective outcomes	High risk	**Quote from publication**: "Participants met ITT criteria if they were randomized to one of the three groups and attended at least one intervention session" **Comment**: missing data reported and reasons explained, imbalance between groups, modified ITT only
Incomplete outcome data (attrition bias) Objective outcomes	High risk	**Quote from publication**: "Participants met ITT criteria if they were randomized to one of the three groups and attended at least one intervention session" **Comment**: missing data reported and reasons explained, imbalance between groups, modified ITT only
Selective reporting (reporting bias)	High risk	**Comment**: number of secondary outcomes (including health-related quality of life and parent weight loss) not published. Data on quality of life and parent weight were provided by author on request
Other bias	Unclear risk	**Comment**: baseline characteristics reported only on the ITT population

Quattrin 2012

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1 **Superiority design**
Participants	**Inclusion criteria**: age 2 to 5 years, BMI $\geq$ 85th percentile for age and gender, normal developmental milestones, 1 participating parent with a BMI $\geq$ 27, parent willing to attend all treatment sessions, speak English or Spanish at a fifth-grade level, and continue care for their child at the same paediatric practice throughout the study **Exclusion criteria**: child's height < 2 standard deviations from the mean for age and gen-

	der, pathologic growth velocity, history of small for gestational age, medications known to affect weight, and child or parent with psychiatric/eating disorder or a pathology preventing performance of physical activity. Families also excluded if the participating mother was pregnant or planning a pregnancy, if parents were acquainted with the family of a child enrolled in the program, or the child's family resided within 0.5 miles from another participating child **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 4 **Treatment before study**: - **Description of interventions:** **Information control**: 13 60-minute sessions over 12 months (4 weekly, 2 bimonthly, 4 monthly, and 3 at 8- to 10-week intervals) followed by a 12-month follow-up (3 meetings at month 16, 20, and 24). Delivered to parents by same leader, content included dietary/physical and sedentary activities education. Recommendations for calorie intake, portion size, weight loss, and physical activity goals. Trained staff engaged the children in active games. Parents received 10 phone calls between meetings by a coach and 3 times in the follow-up period **Family-based weight control intervention**: all aspects of information control described above. In addition, parenting and behavioural intervention, provided strategies to promote behaviour change, including parenting-related techniques (selective ignoring, time out, praising, rewarding, contracting) and changing parental behaviour to facilitate parent and child change (preplanning, stimulus control, shaping, modelling, self monitoring, changing the home environment, social support, changing black-and-white thinking). Before or after the group sessions parents attended a 1:1 meeting with an assigned coach who assisted the parents in shaping behavioural goals. Parents completed icon-based diaries that allowed for shaping of goals by changing the number of icons on the page. Parents were asked to weigh themselves and child twice a week. Group leaders and coaches were closely supervised by investigators
Outcomes	**Outcomes reported in abstract of publication**: BMI per cent, BMI z score, parental BMI
Study details	**Run-in period**: none **Study terminated before regular end (for benefit):** yes (after 105 families recruited as preliminary analyses indicated efficacy) **Study identifier**: NCT01029834
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	**Quote from publication:** "to test the efficacy of an innovative family-based intervention program designed for treating overweight/obese children aged 2 to 5 years and an overweight parent in the primary care setting"
Notes	Slight differences in reported inclusion criteria and in description on interventions (number of sessions) between the 2 publications. Some slight discrepancies between Quattrin 2014 and Quattrin 2012, used Quattrin 2014 data where it was reported

Quattrin 2012 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "blocks of 12 child-parent dyads were randomised by using a random number generator to intervention or IC stratifying for gender" **Comment**: appropriate
Allocation concealment (selection bias)	Unclear risk	**Comment**: no details of allocation concealment
Blinding of participants and personnel (performance bias) Objective outcomes	Low risk	**Quote from publication**: "Pediatricians, blind to group assignment, reviewed the child's progress providing follow up with a standardized letter at 3 months and during a well-child visit at 6 months...". "Parents were not privy to group assignment." **Comment**: investigator assessed
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Comment**: unclear who was the outcome assessor, however unlikely to be affected by blinding
Incomplete outcome data (attrition bias) Objective outcomes	High risk	**Comment**: partially reported and reasons explained. States ITT, but is modified ITT on those completing the intervention and having baseline data. Baseline data are related to participants that received the allocated intervention. Imbalance in attrition
Selective reporting (reporting bias)	High risk	**Comment**: not all outcomes stated are reported, e.g. sugary drink intake, physical activity. Some data reported in figures only, differences in data between publications, some discrepancies in baseline and outcomes between the 2 publications, analyses were adjusted and early publication possibly interim data, however not stated as such
Other bias	Unclear risk	**Comment**: trial stopped early for benefit

Bocca 2012

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1 **Superiority design**
Participants	**Inclusion criteria**: age 3 to 5 years, overweight or obese as defined by the International Obesity Task Force **Exclusion criteria**: mental retardation, severe behavioural problems, or other criteria interfering with participation, overweight or obese owing to known medical conditions or eating disorders according to the Dutch Eating Behaviour Questionnaire **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 1 **Treatment before study**: none **Description of interventions:** **Multidisciplinary intervention**: children and parents received dietary advice, physical activity sessions, and, for parents only, psychological counselling. Dietary advice was 6 x 30-minute sessions with dietitian, advised normocaloric diet based on the required daily intake for this age group, education and advice to improve eating behaviour, personal goals set with feedback on consecutive sessions. Physical activity was 12 x 60-minute group sessions supervised by a physiotherapist; exercise programme focused on an active lifestyle and mimicked the type and intensity of habitual elementary school exercise (e.g. ball playing and dancing to music). Advised to reduced sedentary activities and parents asked to stimulate their child's physical activity to achieve daily physical activity of at least 60 minutes. Behavioural therapy for parents was 6 x 120-minute group sessions guided by psychologist, focus on being a health role mode, working with feasible goals and healthy rewards, change family attitudes towards healthy eating and physical activity. Total of 25 sessions (30 hours) in 16 weeks **Usual care**: children and parents seen by a paediatrician 3 times for 30 to 60 mins each over 16 weeks. Given information on healthy-eating behaviours, advised physical activity 1 hour per day, children advised to play outside every day, walk or bike to school, $\leq$ 2 hours/day screen time
Outcomes	**Outcomes reported in abstract of publication**: change in BMI, BMI z score, waist circumference, waist circumference z score, visceral fat, abdominal subcutaneous fat, HRQoL
Study details	**Run-in period**: none **Study terminated before regular end:** no **Study identifier**: NTR872
Publication details	**Language of publication**: English **Commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	Quote from publication: "to evaluate the long-term effects of a multidisciplinary intervention program in overweight or obese children aged 3-5 years and in children receiving usual-care"

Notes	Bocca 2011 is an abstract that reports 12-month end values (SD). However, these differ from the change values reported in the full publication (Bocca 2012), therefore only the latter data have been extracted Bocca 2014 reports 3-year follow-up but only presents difference between groups. These data have not been extracted Bocca 2014 is a linked publication but reports no eligible outcomes and follow-up at 16 weeks only

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "a computerized randomization procedure in groups of 20, matched by sex." **Comment**: appropriate
Allocation concealment (selection bias)	Unclear risk	**Comment**: not reported
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	**Quote from publication**: "Masking/ blinding: single" **Comment**: self reported outcome measurement. Details of who is blinded not reported
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	**Quote from publication**: "Masking/ blinding: single" **Comment**: investigator assessed. Details of who is blinded not reported
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	**Quote from publication**: "Masking/ blinding: single" **Comment**: self reported outcome measurement. Details of who is blinded not reported
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Quote from publication**: "Masking/ blinding: single" **Comment**: investigator assessed. Low risk of bias from objective outcomes
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	**Comment**: reported and reasons explained
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	**Comment**: reported and reasons explained

Selective reporting (reporting bias)	High risk	**Comment**: at 3 years' follow-up only reports between-group differences
Other bias	Low risk	**Comment**: no other bias

Taveras 2011

Methods	**Cluster randomised controlled clinical trial** **Randomisation ratio**: 1:1 **Superiority design**
Participants	**Inclusion criteria**: age 2.0 to 6.9 years, BMI ≥ 95th percentile or BMI was 85th to < 95th percentile if at least 1 parent was overweight (BMI ≥ 25), received their paediatric care at Harvard Vanguard Medical Associates between August 2006 and October 2008 **Exclusion criteria**: parent or guardian could not respond to interviews in English or Spanish, families were planning to leave Harvard Vanguard Medical Associates, those for whom the primary care clinician thought the intervention was not appropriate, children with chronic medical conditions **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 10 (5 in each cluster) **Treatment before study**: - **Description of interventions:** **High Five for Kids**: primary care behavioural change obesity intervention. Based on the chronic care model, which involved changes to the healthcare system through training of staff and enhancing of electronic record systems. Delivery to participants by paediatric nurse practitioners who used tailored motivational interviewing for four 25-minute, in-person chronic disease management visits and three 15-minute telephone calls in the first year of the intervention (intensive intervention period). Educational modules targeting television viewing and fast-food and sugar-sweetened beverage intake that were matched to a family's stage of readiness to change; printed and electronic tools for self management support; lists of local resources for physical activity; and an interactive website with educational materials, recipes, and other features were used. Small incentives such as water bottles, books, and snack containers. In addition, interested families were offered an electronic television monitoring device to assist with the goal of reducing television viewing. Behavioural goals ('High Five'): (1) < 1 hour television (TV)/video per day, no TV in child's room, (2) ≤ 1 serving of fast-food per week, (3) ≤ 1 serving sugar-sweetened beverages, (4) ≥ 5 servings fruits and vegetables per day, (5) active play at least 1 hour per day Followed by a less intensive maintenance period (no further details) **Usual care control**: well-child care visits and follow-up appointments for weight checks with their paediatrician or a subspecialist (e.g. nutritionist) All participants received USD 20 for completing each telephone interview to collect outcome data. Intervention participants reimbursed for copay incurred at each visit with the nurse practitioners
Outcomes	**Outcomes reported in abstract of publication**: BMI, television viewing, sugar-sweetened beverages intake, fast-food intake

Study details	**Run-in period**: - **Study terminated before regular end:** no **Study identifier**: NCT00377767
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	Quote from publication: "to assess the extent to which a primary care-based intervention, compared with the usual care control condition, resulted in a smaller increase in BMI and improvement in obesity-related behaviours among children aged 2 through 6 years at elevated risk of obesity"
Notes	Publication reports 1-year findings of a 2-year study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "divided the practices into the biggest 4 and smallest 6, then matched within those groups as closely as possible on racial/ethnic composition. Within each of 5 pairs, a computerized routine randomly allocated one practice to the intervention group and one to the usual care control group ..." **Comment**: appropriate randomisation
Allocation concealment (selection bias)	Unclear risk	**Comment**: no details
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	**Comment**: self reported outcome measurement, NCT record states double blind
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	**Comment**: investigator-assessed outcomes, NCT record states double blind
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	**Comment**: self reported outcome measurement, NCT record states double blind
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Comment**: investigator-assessed outcomes, unlikely to be affected by potential lack of outcome assessor blinding

Taveras 2011 (*Continued*)

Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	**Comment**: missing data reported but reasons not explained, baseline variables reported only on those completing the study. Some discrepancies in baseline outcomes and SD/SE, possibly different numbers used
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	**Comment**: missing data reported but reasons not explained, baseline variables reported only on those completing the study. Some discrepancies in baseline outcomes and SD/SE, possibly different numbers used
Selective reporting (reporting bias)	Low risk	**Comment**: all outcomes reported as stated
Other bias	Low risk	**Comment**: no other bias

Stark 2011

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1 **Superiority design**
Participants	**Inclusion criteria**: age 2 to 5 years, BMI $\geq$ 95th percentile but $\leq$ 100% above the mean BMI, at least 1 parent with a BMI $\geq$ 25, medical clearance from the child's paediatrician **Exclusion criteria**: non-English speaking; living > 50 miles from the medical centre; disability or illness that would interfere with at least moderate physical activity; medical condition/medication associated with weight gain; or currently enrolled in another weight-control program **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 1 **Treatment before study**: - **Description of interventions** (**L**earning about **A**ctivity and **U**nderstanding **N**utrition for **C**hild **H**ealth (LAUNCH): **Phase 1** (intensive intervention): 12 weekly sessions alternating between group-based clinic sessions (parent and child concurrent groups) and individual home visits. Parent-group clinic sessions (90 min each) addressed dietary education, physical activity, and parenting skills including behavioural control strategies such as stimulus control. Goals for calories, screen time, and physical activity set. Pedometer and diet diary data were used as feedback tools. Given 14-day supply of vegetables at clinic sessions. Delivered by a psychologist. Children were seen concurrently in a group format. Received nutrition education through games and art activities, tried new foods during a structured meal, and completed 15 min of moderate to vigorous activity. In-home sessions (60 to 90 min each) were designed to support generalisation of the clinic-taught skills to the home environment **Phase 2** (maintenance): 12 weeks of every-other-week sessions, alternating between

	group sessions in clinic and home sessions. Focused on helping families continue to make or maintain changes in eating and activity by identifying barriers and problem-solving with the families on using strategies taught during phase 1 to address these barriers **Control** (enhanced standard of care): Paediatric counselling to deliver dietary and physical activity recommendations outlined by the American Academy of Pediatrics. One 45-minute session following a scripted manual to review child's growth chart and explain BMI. Recommendations made were: (i) $\leq$ 2 h/day of screen time; (ii) 60 min/day of active play; (iii) eliminating soda and limiting juice to 4 oz/day); (iv) providing $\geq$ 5 servings/day of fruits and vegetables; (v) limiting eating out; and (vi) appropriate portion sizes for preschoolers. Given a 1-page healthy food and activity brochure
Outcomes	**Outcomes reported in abstract of publication**: change in BMI z score, BMI percentile, weight change, parent weight change
Study details	**Run-in period**: - **Study terminated before regular end:** no **Study identifier**: NCT01018121
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	Quote from publication: "to conduct a pilot randomized clinical trial of LAUNCH compared to an enhanced standard of care condition (Pediatrician Counseling; PC)"
Notes	Described as a pilot study

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "random numbers table" **Comment**: appropriate
Allocation concealment (selection bias)	Low risk	**Quote from publication**: "Randomization was … concealed until all baseline assessments were completed" **Comment**: Information from author: "randomization was conducted by a study coordinator in a separate research lab within the department … Once all participants were consented she would randomize the children to treatment condition in order of the date their consent form was signed"

Stark 2011 (*Continued*)

Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	**Quote from publication**: "single blind (outcome assessor)" "Randomization was … concealed until all baseline assessments were completed" **Comment**: self reported outcome measurement. Participants and personnel not blind
Blinding of participants and personnel (performance bias) Objective outcomes	High risk	**Quote from publication**: "single blind (outcome assessor)" "Randomization was … concealed until all baseline assessments were completed" **Comment**: investigator assessed. Participants and personnel not blind
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	**Quote from publication**: "single blind (outcome assessor)" **Comment**: self reported outcome measurement
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Quote from publication**: "by trained personnel … who aware of the child's treatment condition" **Comment**: investigator assessed. Low risk of bias from objective outcomes
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	**Comment**: reported and reasons explained
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	**Comment**: reported and reasons explained
Selective reporting (reporting bias)	Low risk	**Comment**: physical activity reported narratively only, data not presented. Author provided data on request and confirmed all outcomes measured by the study were reported
Other bias	Low risk	**Comment**: no other bias

Lanigan 2010

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1 **Superiority design**
Participants	**Inclusion criteria**: attending family centres, BMI ≥ 91st percentile or weight had crossed centiles upwards on the UK-WHO growth reference, age 1 to 5 years **Exclusion criteria**: -

	Diagnostic criteria: as above
Interventions	**Number of study centres**: 1 **Treatment before study**: none **Description of interventions:** **Trim Tots healthy lifestyle programme**. Community-based lifestyle intervention. 2-hour sessions delivered 2x weekly for 3 months then weekly for 3 months. Included nutrition education, physical activity, and behavioural-change components, emphasis on family involvement and learning through art and play. Education delivered through interactive teaching sessions and practical workshops. Behaviour change was encouraged by setting SMART (specific, measurable, achievable, realistic, and timely) goals to achieve small sustainable changes in diet and activity **Wait-list control**
Outcomes	**Outcomes reported in abstract of publication**: BMI, BMI z score
Study details	**Run-in period**:- **Study terminated before regular end:** no **Study identifier**: NCT00675662
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** conference abstract/journal supplement
Stated aim for study	Quote from publication: "to reduce obesity risk in children aged 1-5 years"
Notes	Minimal data from abstract, differences between groups reported only. Data for change in BMI, weight, and waist circumference at 6 months' follow-up provided by author. Data on secondary outcomes not yet available. Full publication in preparation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "randomly assigned by an independent statistician by a computer-generated permuted block design." **Comment**: appropriate
Allocation concealment (selection bias)	Low risk	**Quote**: "The randomization schedule, generated by random permuted blocks and prepared by a member of the team not involved in data collection, was assigned using sealed, numbered and opaque envelopes" **Comment**: appropriate

Lanigan 2010 (*Continued*)

Blinding of participants and personnel (performance bias) Objective outcomes	High risk	**Quote**: "waiting list control design … all children were invited for measurements regardless of their participation status (immediate or delayed start)" **Comment**: participants and personnel aware of allocation
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Quote**: "Research staff employed by the childhood nutrition research centre at UCl ICH carried out all measurements and were blind to subject allocation" **Comment**: investigator assessed. Low risk of bias from objective outcomes
Incomplete outcome data (attrition bias) Objective outcomes	High risk	**Comment**: numbers and reasons provided, imbalance in loss to follow-up between groups. States analysis by ITT, although some uncertainty
Selective reporting (reporting bias)	High risk	**Comment**: difference between groups reported only. Number of secondary outcomes not reported
Other bias	Low risk	**Comment**: no other bias

Kelishadi 2009

Methods	**Parallel randomised controlled clinical trial** **Randomisation ratio**: 1:1:1 **Superiority design**
Participants	**Inclusion criteria**: identified as obese during routine physical examination at preschool entry, BMI ≥ age- and sex-specific 95th percentile (CDC growth charts), pre-pubertal (Tanner stage 1) **Exclusion criteria**: pubertal stage > SMR 1, syndromal obesity, endocrine disorders, presence of any physical disability, and/or history of chronic medication use **Diagnostic criteria**: as above
Interventions	**Number of study centres**: 1 **Treatment before study**: none **Description of interventions:** All attended 6 consecutive monthly family-centred education sessions about healthy lifestyle (healthy nutrition and increasing physical activity) conducted by a paediatrician and a nutritionist. Followed-up twice a year until 3 years after baseline **1. Dairy-rich diet group**: > 800 mg calcium/day recommended, no change on energy or macronutrient intake, advised to obtain calcium from low-fat and regular milk, cheese, and yogurt, liquid and solid curd **2. Energy-restricted group**: caloric restriction regimen with an energy content restricted

	to the calorie requirement for height (reference provided) **3. Control**: no dietary recommendation other than what was discussed in the healthy lifestyle education sessions
Outcomes	**Outcomes reported in abstract of publication**: BMI z score, waist circumference, serum triglycerides, insulin levels, HDL cholesterol, insulin resistance
Study details	**Run-in period**: - **Study terminated before regular end:** no
Publication details	**Language of publication**: English **Non-commercial funding** **Publication status:** peer-reviewed journal
Stated aim for study	Quote from publication: "to determine the short- and long-term results of a randomized controlled trial of a dairy-rich diet on generalized and abdominal obesity, and the components of the metabolic syndrome among obese prepubescent children during a 6-month intervention and 3 years of follow-up"
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote from publication**: "random allocation was conducted by computer-generated random numbers" **Comment**: appropriate
Allocation concealment (selection bias)	Unclear risk	**Comment**: not reported
Blinding of participants and personnel (performance bias) Subjective outcomes	Unclear risk	**Comment**: not reported, self reported outcome measurement
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	**Comment**: not reported, self reported outcome measurement
Blinding of outcome assessment (detection bias) Subjective outcomes	Unclear risk	**Quote from publication**: "all follow-up procedures were conducted by a physician and a research assistant who were not included in the intervention team. These outcome assessors and data analysts were unaware of group allocation" **Comment**: self reported outcome measurement

Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	**Quote from publication**: "all follow-up procedures were conducted by a physician and a research assistant who were not included in the intervention team. These outcome assessors and data analysts were unaware of group allocation" **Comment**: investigator assessed
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	**Comment**: reported and reasons explained
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	**Comment**: reported and reasons explained
Selective reporting (reporting bias)	High risk	**Comment**: per cent body fat only reported at selected time points, some data presented in figures only, some outcomes not reported
Other bias	Unclear risk	**Comment**: pre-selection by random selection taking into account socioeconomic factors, different parts of the city

Note: where the judgement is 'Unclear' and the description is blank, the trial did not report that particular outcome.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Berner 2015	Study design not RCT with 6 months' follow-up
ChiCTR-TRC-12001880	Participants
NCT00528164	Participants
NCT01515254	Intervention
NCT01546727	Participants
NCT01552642	Intervention
NCT01610219	Participants
NCT01792531	Participants

(*Continued*)

NCT02373670	Intervention
Resnicow 2012	Intervention
Van Allen 2014	Study design not RCT with 6 months' follow-up
Wake 2012	Participants

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

NCT00916318

Trial name or title	Overweight and Obesity in Preschool Children, Prevalence and Prevention - Family Based Health Interventions for Child Health **Acronym**: LOOPS (Lund Overweight and Obesity Preschool Study)
Methods	**Type of study:** interventional **Allocation**: randomised **Intervention model**: parallel **Masking**: open label **Primary purpose**: treatment
Participants	**Condition**: overweight, obese **Enrolment**: estimated 240 (160 overweight, 80 obese) **Inclusion criteria**: children aged 4 to 6 years with overweight and obesity **Exclusion criteria**: do not understand written and spoken Swedish well enough to participate in group activities
Interventions	**Intervention(s)**: All start with a 2-hour lecture with general facts about overweight in children (GFO), performed by health professionals. Also access to a website, Healthy Children (HC), with general information about diet and exercise recommendations Obese children randomised to either: 1) Better balance everyday - parenthood and lifestyle (BBE), run by a clinical psychologist, parents attend six 2-hour sessions over 12 months 2) Lighter Living (LiLi), run by an occupational therapist, based on the theory that alterations in the parents' everyday life will induce changes that will gradually lead to a normalisation of their children's weight. Groups meet for 13 2-hour sessions over 12 months Overweight children randomised to 1 of 3 groups: 1) BBE as above 2) Website only: information on health food and physical activity, based on national guidelines and recommendations for preschool children whether overweight or not; parents can ask questions to paediatrician, a dietitian, a psychologist, or an occupational therapist 3) Control (general lecture only)

NCT00916318 (*Continued*)

	Parents are invited to attend group meetings with the general purpose of supporting the children ing accomplishing preferred lifestyle changes, both in the short and long run
Outcomes	**Primary outcome(s)**: change in BMI z score **Secondary outcome(s)**: dietary and exercise patterns, waist circumference, insulin resistance, dietary hormones, faecal microflora **Other outcome(s)**: parent change in BMI, perception of their own health, parent stress, child feeding and exercise habits
Starting date	**Study start date**: August 2008 **Study completion date**: November 2015
Contact information	**Responsible party/principal investigator**: Kristina Thorngren-Jerneck, Lund University Childrens' Hospital, Sweden
Study identifier	**NCT number:** NCT00916318
Official title	Overweight and obesity in preschool children, prevalence and prevention - family based health interventions for child health (trial document) LOOPS - Lund Overweight and Obesity Preschool Study (published protocol)
Stated purpose of study	Quote: "to evaluate if a family-based intervention, targeting parents of preschool children with overweight and obesity, has a long-term positive effect on weight development of the children"
Notes	

NCT01698606

Trial name or title	**Acronym**: FOR HEALTH: A Family-ORiented Healthy Eating, Activity and Lifestyle Intervention for Overweight Preschool Children
Methods	**Type of study:** interventional **Allocation**: randomised **Intervention model**: parallel assignment **Masking**: open label **Primary purpose**: open label
Participants	**Condition**: childhood obesity **Enrolment**: estimated 28 **Inclusion criteria**: aged 2 to 6 years with primary overweight or obesity, BMI $\geq$ 85th percentile for age and sex on 2010 WHO Growth Charts for Canada, family meets Readiness for Change criteria, contemplation or higher stage, according to Prochaska's Transtheoretical Model, $\geq$ 1 parent/caregiver committed to attending all program sessions with the child **Exclusion criteria**: chronic medical conditions (physical, developmental, or psychological) potentially impacting program participation or associated with a potentially increased risk in participation, regular use of medications that could limit extent of study participation, other concurrent or recently (last 12 months) received obesity treatment, inability to understand English, living outside of the greater London, Ontario, area

NCT01698606 (*Continued*)

Interventions	**Intervention(s)**: multidisciplinary, family-centred lifestyle intervention with behavioural counselling. Parent/caregiver education with skill training and practical activities revolving around healthy dietary choices, establishing an active versus a sedentary lifestyle, and behavioural aspects, while children will be engaged in active play **Comparator(s)**: wait-list control
Outcomes	**Primary outcome(s)**: BMI z score **Secondary outcome(s)**: change in Quality of Life Scores (PedsQL 4.0), change in physical activity score, change in parent-reported daily screen time, change in fruit and vegetable consumption, change in dairy product consumption, change in grain product consumption, change in consumption of sugar-sweetened beverages, change in per cent over BMI **Other outcome(s)**: -
Starting date	**Study start date**: January 2013 **Study completion date**: August 2016
Contact information	**Responsible party/principal investigator**: Lawson Health Research Institute/Dirk Bock
Study identifier	**NCT number**: NCT01698606
Official title	FOR HEALTH: A Family-ORiented Healthy Eating, Activity and Lifestyle Training With Hands-on Experience for Overweight and Obese Preschool Children and Their Families - a Pilot Trial
Stated purpose of study	Quote: "to investigate whether a community-based, 6-month intervention for overweight and obese preschool children 2-6 years of age and their families, referred by their family physicians, will be successful in reducing the participants' degree of overweight (BMI z score)."
Notes	

NCT02292602

Trial name or title	**Acronym**: -
Methods	**Type of study:** interventional **Allocation**: interventional **Intervention model**: parallel assignment **Masking**: single blind (outcomes assessor) **Primary purpose**: treatment
Participants	**Condition**: paediatric obesity **Enrolment**: estimated 72 **Inclusion criteria**: family receiving services at Detroit-based WIC clinics; 2 to 4 years, 7 months; BMI > 85th percentile; 1 primary caregiver willing to participate and whose BMI > 25; English-speaking; medical clearance to participate **Exclusion criteria**: child or caregiver: participating in a different weight management program; condition that precludes participation in moderate-level activity; diagnosed with a weight-affecting health condition; taking weight-affecting medications; diagnosed with a developmental delay or disability; receiving treatment

NCT02292602 (*Continued*)

	for severe psychopathology; plans to be out of town for more than 2 weeks of the first 4 months of their research participation; plans to move from Detroit in the next 7 months
Interventions	**Intervention(s)**: 4-month, 14-session behavioural weight control intervention. 9 group-based sessions held at WIC clinic; 5 individual visits (4 at home, 1 at a food market). Intervention includes behavioural weight loss, child behaviour management, life skills (e.g. budgeting and time management) via experiential learning **Comparator(s)**: control: standard of care at WIC clinic
Outcomes	**Primary outcome(s)**: feasibility (attendance and attrition); perceived acceptability of the program; change in child BMI z score, change in caregiver BMI **Secondary outcome(s)**: change in child diet, change in child activity, change in caregiver diet, change in caregiver activity, change in caregiver feeding, change in caregiver stress, change in home food environment **Other outcome(s)**: -
Starting date	**Study start date**: February 2014 **Study completion date**: January 2016
Contact information	**Responsible party/principal investigator**: Wayne State University/Elizabeth Kuhl
Study identifier	**NCT number**: NCT02292602
Official title	Developing a preschool obesity intervention for families enrolled in WIC
Stated purpose of study	Quote: "to examine the feasibility, acceptability, and preliminary efficacy of a community and home-based preschool obesity intervention for families enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)"
Notes	

Reifsnider 2012

Trial name or title	**Acronym**: -
Methods	**Type of study:** - **Allocation**: randomised **Intervention model**: parallel assignment **Masking**: - **Primary purpose**: treatment
Participants	**Condition**: obesity **Enrolment**: planned 100, actual 55 **Inclusion criteria**: age 2 to 4 years, BMI > 95% for age and sex **Exclusion criteria**: -
Interventions	**Intervention(s)**: 6 classes at WIC clinics covering: reading food labels, identifying appropriate types and amounts of food, feeding picky eaters, basics of temperament, showing affection other than through food, ways to cook healthier food, how to be active when indoors, limiting screen time to 1 hour, discipline,

	importance of regular meal times and eating as a family. Theoretically based. Duration 6 months **Comparator(s)**: standard WIC nutrition education
Outcomes	**Primary outcome(s)**: BMI **Secondary outcome(s)**: dietary intake, food availability, hours of screen time, stimulation in home, parental feeding style, acculturation of parents, safety of neighbourhood environment **Other outcome(s)**: -
Starting date	**Study start date**: - **Study completion date**: -
Contact information	**Responsible party/principal investigator**: Arizona State University/Elizabeth A Reifsnider
Study identifier	-
Official title	Reducing childhood obesity among WIC recipients
Stated purpose of study	Quote: "to determine the impact of an intervention delivered in neighbourhood Special Supplemental Nutrition Program for Women, Infants and Children (WIC) clinics on childhood obesity (BMI > 95 percent for age and sex) in 2-4 year old children"
Notes	

BMI: body mass index; PedsQL: Pediatric Quality of Life Inventory; WHO: World Health Organization; WIC: women, infants, and children

DATA AND ANALYSES

Comparison 1. Multicomponent intervention versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Changes in BMI z score	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 End of intervention (6-12 months)	4	210	Mean Difference (IV, Random, 95% CI)	-0.26 [-0.37, -0.16]
1.2 12-18 months follow-up (6-8 months post intervention)	4	202	Mean Difference (IV, Random, 95% CI)	-0.38 [-0.58, -0.19]
1.3 24 months follow-up (12 months post intervention)	1	96	Mean Difference (IV, Random, 95% CI)	-0.25 [-0.40, -0.10]
2 Changes in BMI	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 End of intervention (6-12 months)	1	64	Mean Difference (IV, Random, 95% CI)	-0.40 [-0.85, 0.05]
2.2 12 months follow-up (8 months post intervention)	1	57	Mean Difference (IV, Random, 95% CI)	-1.0 [-1.79, -0.21]
3 Changes in % over BMI	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 End of intervention (12 months)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 18 months follow-up (6 months post intervention)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 24 months follow-up (12 months post intervention)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Changes in BMI percentile	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 End of intervention (6 months)	2	50	Mean Difference (IV, Random, 95% CI)	-1.54 [-2.82, -0.26]
4.2 12 months follow-up (6 months post intervention)	2	49	Mean Difference (IV, Random, 95% CI)	-3.47 [-5.11, -1.82]
5 Changes in body weight	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 End of intervention (6-12 months)	4	210	Mean Difference (IV, Random, 95% CI)	-1.18 [-1.91, -0.45]
5.2 12-18 months follow-up (6-8 months post intervention)	4	202	Mean Difference (IV, Random, 95% CI)	-2.81 [-4.39, -1.22]
5.3 24 months follow-up (12 months intervention)	1	96	Mean Difference (IV, Random, 95% CI)	-1.60 [-2.42, -0.78]
6 Changes in parental BMI	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
6.1 End of intervention (6-12 months)	2	113	Mean Difference (IV, Random, 95% CI)	0.00 [-2.52, -1.48]
6.2 12-18 months follow-up (6 months post intervention)	2	112	Mean Difference (IV, Random, 95% CI)	-2.08 [-2.65, -1.51]
6.3 24 months follow-up (12 months post intervention)	1	96	Mean Difference (IV, Random, 95% CI)	-2.0 [-2.57, -1.43]
7 Changes in parental weight	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
7.1 End of intervention (6-12 months)	3	146	Mean Difference (IV, Random, 95% CI)	-4.69 [-7.27, -2.11]

7.2 12-18 months follow-up (6 months post intervention)	2	49	Mean Difference (IV, Random, 95% CI)	-5.14 [-8.96, -1.33]
7.3 24 months follow-up (12 months post intervention)	1	96	Mean Difference (IV, Random, 95% CI)	-6.7 [-8.42, -4.98]
8 Changes in health-related quality of life: DUX 25			Other data	No numeric data
8.1 12 months follow-up (8 months post intervention)			Other data	No numeric data
9 Changes in health-related quality of life: CHQ-PF50			Other data	No numeric data
9.1 12 months follow-up (8 months post intervention)			Other data	No numeric data
10 Changes in health-related quality of life: PEDsQL physical functioning	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
10.1 End of intervention (6 months)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10.2 12 months follow-up (6 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
11 Changes in health-related quality of life: PEDsQL total score	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
11.1 End of intervention (6 months)	1	28	Mean Difference (IV, Random, 95% CI)	4.35 [-2.35, 11.06]
11.2 12 months follow-up (6 months post intervention)	1	28	Mean Difference (IV, Random, 95% CI)	0.74 [-5.80, 7.27]
12 Changes in waist circumference	2		Mean Difference (IV, Random, 95% CI)	Totals not selected
12.1 End of intervention (6 months)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
12.2 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
13 Changes in waist circumference z-score	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
13.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
14 Changes in hip circumference	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
14.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
15 Changes in hip circumference z-score	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
15.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
16 Changes in upper arm circumference	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
16.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
17 Changes in per cent body fat	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
17.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
18 Changes in fat-free mass	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

18.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
19 Changes in visceral fat	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
19.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
20 Changes in subcutaneous fat	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
20.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
21 Changes in outdoor active play	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
21.1 End of intervention (12 months)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
22 Changes in steps	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
22.1 12 months follow-up (8 months post intervention)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
23 Changes in physical activity, moderate	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
23.1 At end of intervention (6 months)	2	48	Mean Difference (IV, Random, 95% CI)	6.57 [-0.47, 13.61]
23.2 12 months follow-up (6 months post intervention)	2	46	Mean Difference (IV, Random, 95% CI)	10.14 [-3.80, 24.08]
24 Changes in physical activity, vigorous	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
24.1 End of intervention (6 months)	2	48	Mean Difference (IV, Random, 95% CI)	2.78 [-1.30, 6.85]
24.2 12 months follow-up (6 months post intervention)	2	47	Mean Difference (IV, Random, 95% CI)	7.40 [2.81, 12.00]
25 Changes in sugar-sweetened drinks	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
25.1 End of intervention (12 months)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
26 Changes in fruit and vegetable intake	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
26.1 End of intervention (12 months)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
27 Changes in TV and video viewing	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
27.1 End of intervention (12 months)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Comparison 2. Diet intervention versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Changes in BMI z score	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
1.1 Dairy rich: end of intervention (6 months)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

1.2 Energy restricted: end of intervention (6 months)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.3 Dairy rich: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.4 Energy restricted: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.5 Dairy rich: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.6 Energy restricted: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.7 Dairy rich: 36 months follow-up (30 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.8 Energy restricted: 36 months follow-up (30 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2 Changes in waist circumference	1	Mean Difference (IV, Random, 95% CI)	Totals not selected
2.1 Dairy rich: end of intervention (6 months)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Energy restricted: end of intervention (6 months)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.3 Dairy rich: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.4 Energy restricted: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.5 Dairy rich: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.6 Energy restricted: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.7 Dairy rich: 36 months follow-up (30 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.8 Energy restricted: 36 months follow-up (30 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3 Changes in per cent body fat	1	Mean Difference (IV, Random, 95% CI)	Totals not selected
3.1 Dairy rich: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3.2 Energy restricted: 12 months follow-up (6 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

3.3 Dairy rich: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3.4 Energy restricted: 24 months follow-up (18 months post intervention)	1	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

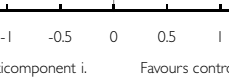
Analysis 1.1. Comparison 1 Multicomponent intervention versus control, Outcome 1 Changes in BMI z score.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 1 Changes in BMI z score

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg/m²]	Control N	Mean(SD)[kg/m²]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6-12 months)							
Stark 2014 (1)	10	-0.37 (0.42)	6	-0.07 (0.18)		12.1 %	-0.30 [-0.60, 0.00]
Stark 2014 (2)	11	-0.25 (0.25)	6	-0.07 (0.18)		22.9 %	-0.18 [-0.39, 0.03]
Quattrin 2012	46	-0.45 (0.3)	50	-0.21 (0.4)		41.3 %	-0.24 [-0.38, -0.10]
Stark 2011	7	-0.49 (0.36)	10	0.1 (0.32)		9.9 %	-0.59 [-0.92, -0.26]
Lanigan 2010	36	-0.2 (0.5)	28	0.01 (0.6)		13.9 %	-0.21 [-0.48, 0.07]
Subtotal (95% CI)	**110**		**100**			**100.0 %**	**-0.26 [-0.37, -0.16]**
Heterogeneity: Tau² = 0.00; Chi² = 4.65, df = 4 (P = 0.33); I² =14%							
Test for overall effect: Z = 4.77 (P < 0.00001)							
2 12-18 months follow-up (6-8 months post intervention)							
Stark 2014 (3)	10	-0.5 (0.43)	6	-0.03 (0.36)		15.9 %	-0.47 [-0.86, -0.08]
Stark 2014 (4)	11	-0.59 (0.75)	6	-0.03 (0.36)		10.4 %	-0.56 [-1.09, -0.03]
Bocca 2012	32	-0.6 (0.5)	25	-0.3 (0.5)		24.8 %	-0.30 [-0.56, -0.04]
Quattrin 2012	46	-0.45 (0.36)	50	-0.25 (0.4)		35.3 %	-0.20 [-0.35, -0.05]
Stark 2011	7	-0.37 (0.41)	9	0.4 (0.49)		13.6 %	-0.77 [-1.21, -0.33]
Subtotal (95% CI)	**106**		**96**			**100.0 %**	**-0.38 [-0.58, -0.19]**
Heterogeneity: Tau² = 0.02; Chi² = 7.67, df = 4 (P = 0.10); I² =48%							
Test for overall effect: Z = 3.85 (P = 0.00012)							
3 24 months follow-up (12 months post intervention)							
Quattrin 2012	46	-0.5 (0.36)	50	-0.25 (0.4)		100.0 %	-0.25 [-0.40, -0.10]
Subtotal (95% CI)	**46**		**50**			**100.0 %**	**-0.25 [-0.40, -0.10]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.22 (P = 0.0013)							



(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

Analysis 1.2. Comparison 1 Multicomponent intervention versus control, Outcome 2 Changes in BMI.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 2 Changes in BMI

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg/m²]	Control N	Mean(SD)[kg/m²]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6-12 months)							
Lanigan 2010	36	-0.6 (0.8)	28	-0.2 (1)		100.0 %	-0.40 [-0.85, 0.05]
Subtotal (95% CI)	**36**		**28**			**100.0 %**	**-0.40 [-0.85, 0.05]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.73 (P = 0.084)							
2 12 months follow-up (8 months post intervention)							
Bocca 2012	32	-1 (1.4)	25	0 (1.6)		100.0 %	-1.00 [-1.79, -0.21]
Subtotal (95% CI)	**32**		**25**			**100.0 %**	**-1.00 [-1.79, -0.21]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.47 (P = 0.013)							

Analysis 1.3. Comparison 1 Multicomponent intervention versus control, Outcome 3 Changes in % over BMI.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 3 Changes in % over BMI

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg/m^2]	Control N	Mean(SD)[kg/m^2]	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 End of intervention (12 months)						
Quattrin 2012	46	-5.5 (7.35)	50	0.1 (7.1)		-5.60 [-8.50, -2.70]
2 18 months follow-up (6 months post intervention)						
Quattrin 2012	46	-3.6 (7.99)	50	1.7 (7.65)		-5.30 [-8.43, -2.17]
3 24 months follow-up (12 months post intervention)						
Quattrin 2012	46	-2.4 (7.99)	50	4.1 (7.65)		-6.50 [-9.63, -3.37]

Analysis 1.4. Comparison 1 Multicomponent intervention versus control, Outcome 4 Changes in BMI percentile.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 4 Changes in BMI percentile

Study or subgroup	Multicomponent intervent. N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6 months)							
Stark 2014 (1)	10	-2.5 (3.5)	6	-0.1 (0.7)		22.0 %	-2.40 [-4.64, -0.16]
Stark 2014 (2)	11	-0.8 (1.2)	6	-0.1 (0.7)		50.4 %	-0.70 [-1.60, 0.20]
Stark 2011	7	-2.1 (1.9)	10	0.3 (2)		27.6 %	-2.40 [-4.28, -0.52]
Subtotal (95% CI)	**28**		**22**			**100.0 %**	**-1.54 [-2.82, -0.26]**
Heterogeneity: $Tau^2 = 0.63$; $Chi^2 = 3.85$, df = 2 (P = 0.15); $I^2 = 48\%$							
Test for overall effect: Z = 2.36 (P = 0.018)							
2 12 months follow-up (6 months post intervention)							
Stark 2014 (3)	10	-4 (3.9)	6	0.2 (1.1)		40.9 %	-4.20 [-6.77, -1.63]
Stark 2014 (4)	11	-5.1 (11.3)	6	0.2 (1.1)		6.0 %	-5.30 [-12.04, 1.44]
Stark 2011	7	-1.1 (1.9)	9	1.6 (2.7)		53.1 %	-2.70 [-4.96, -0.44]
Subtotal (95% CI)	**28**		**21**			**100.0 %**	**-3.47 [-5.11, -1.82]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.04$, df = 2 (P = 0.59); $I^2 = 0.0\%$							
Test for overall effect: Z = 4.13 (P = 0.000036)							

(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

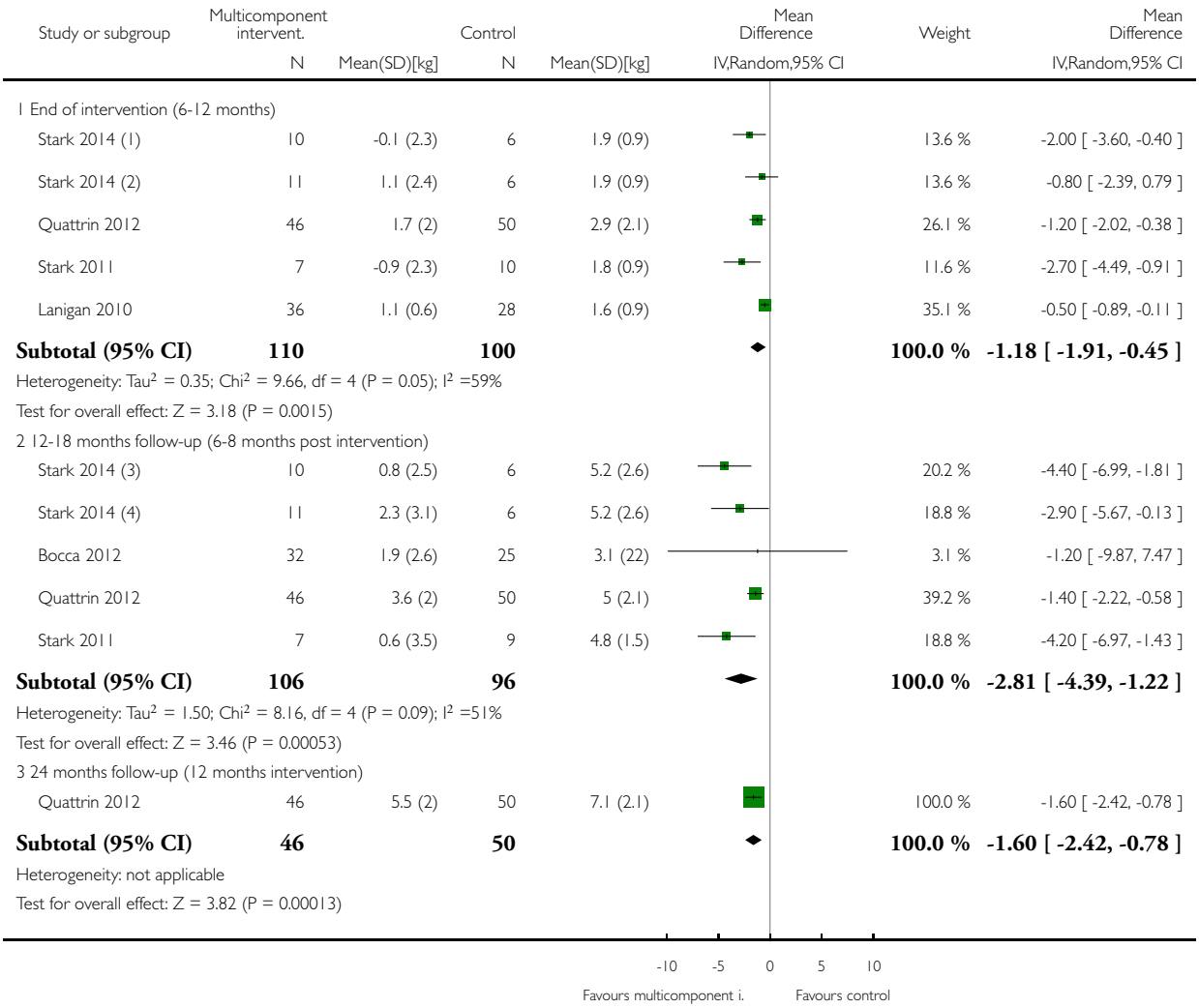
(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

Analysis 1.5. Comparison 1 Multicomponent intervention versus control, Outcome 5 Changes in body weight.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 5 Changes in body weight



(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

Analysis 1.6. Comparison 1 Multicomponent intervention versus control, Outcome 6 Changes in parental BMI.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 6 Changes in parental BMI

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg/m^2]	Control N	Mean(SD)[kg/m^2]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6-12 months)							
Stark 2011	7	-2.8 (1.7)	10	-0.8 (1.8)		9.5 %	-2.00 [-3.68, -0.32]
Quattrin 2012	46	-2.3 (1.31)	50	-0.3 (1.41)		90.5 %	-2.00 [-2.54, -1.46]
Subtotal (95% CI)	**53**		**60**			**100.0 %**	**-2.00 [-2.52, -1.48]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.00, df = 1 (P = 1.00); I^2 =0.0%							
Test for overall effect: Z = 7.57 (P < 0.00001)							
2 12-18 months follow-up (6 months post intervention)							
Stark 2011	7	-3.1 (1.3)	9	0 (2.8)		7.5 %	-3.10 [-5.17, -1.03]
Quattrin 2012	46	-2.1 (1.44)	50	-0.1 (1.41)		92.5 %	-2.00 [-2.57, -1.43]
Subtotal (95% CI)	**53**		**59**			**100.0 %**	**-2.08 [-2.65, -1.51]**
Heterogeneity: Tau^2 = 0.01; Chi^2 = 1.01, df = 1 (P = 0.31); I^2 =1%							
Test for overall effect: Z = 7.17 (P < 0.00001)							
3 24 months follow-up (12 months post intervention)							
Quattrin 2012	46	-2 (1.44)	50	0 (1.41)		100.0 %	-2.00 [-2.57, -1.43]
Subtotal (95% CI)	**46**		**50**			**100.0 %**	**-2.00 [-2.57, -1.43]**
Heterogeneity: not applicable							
Test for overall effect: Z = 6.87 (P < 0.00001)							

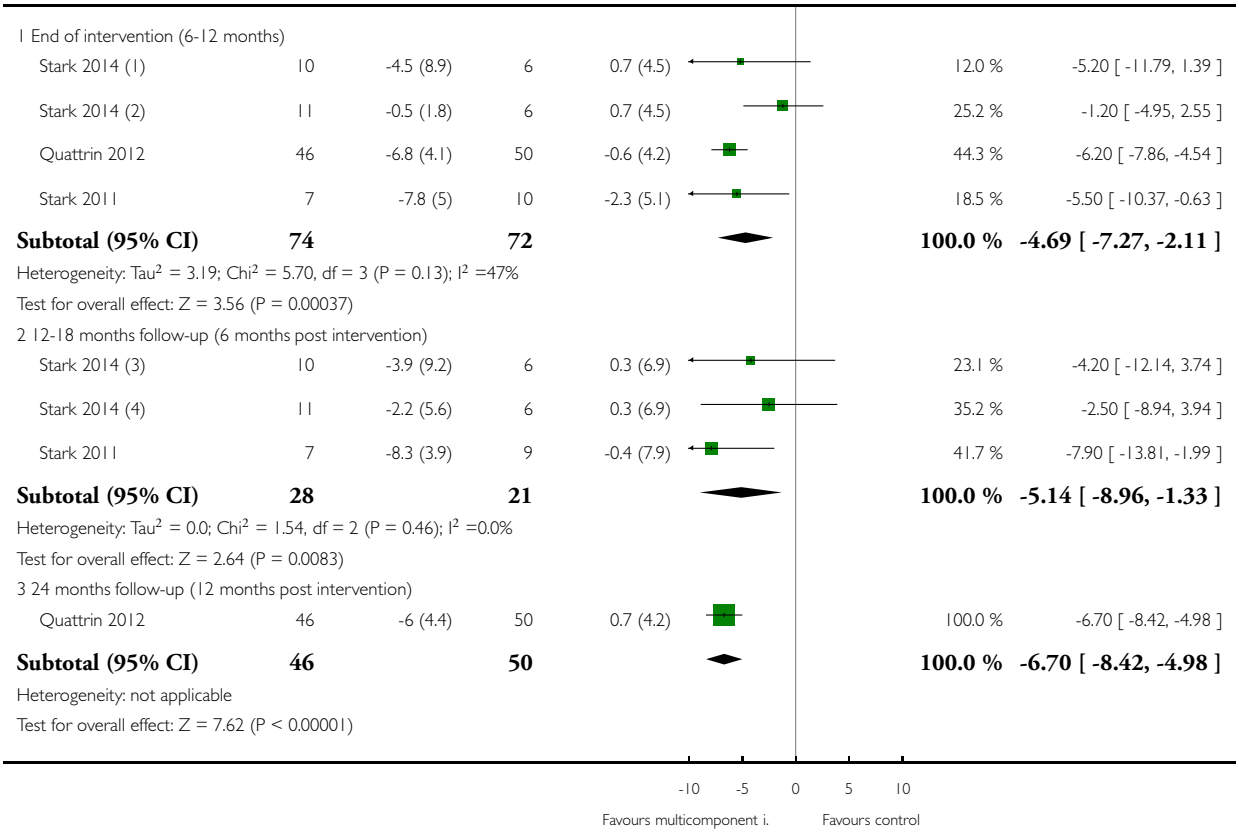
Analysis 1.7. Comparison 1 Multicomponent intervention versus control, Outcome 7 Changes in parental weight.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 7 Changes in parental weight

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg]	Control N	Mean(SD)[kg]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6-12 months)							
Stark 2014 (1)	10	-4.5 (8.9)	6	0.7 (4.5)		12.0 %	-5.20 [-11.79, 1.39]
Stark 2014 (2)	11	-0.5 (1.8)	6	0.7 (4.5)		25.2 %	-1.20 [-4.95, 2.55]
Quattrin 2012	46	-6.8 (4.1)	50	-0.6 (4.2)		44.3 %	-6.20 [-7.86, -4.54]
Stark 2011	7	-7.8 (5)	10	-2.3 (5.1)		18.5 %	-5.50 [-10.37, -0.63]
Subtotal (95% CI)	**74**		**72**			**100.0 %**	**-4.69 [-7.27, -2.11]**
Heterogeneity: Tau^2 = 3.19; Chi^2 = 5.70, df = 3 (P = 0.13); I^2 =47%							
Test for overall effect: Z = 3.56 (P = 0.00037)							
2 12-18 months follow-up (6 months post intervention)							
Stark 2014 (3)	10	-3.9 (9.2)	6	0.3 (6.9)		23.1 %	-4.20 [-12.14, 3.74]
Stark 2014 (4)	11	-2.2 (5.6)	6	0.3 (6.9)		35.2 %	-2.50 [-8.94, 3.94]
Stark 2011	7	-8.3 (3.9)	9	-0.4 (7.9)		41.7 %	-7.90 [-13.81, -1.99]
Subtotal (95% CI)	**28**		**21**			**100.0 %**	**-5.14 [-8.96, -1.33]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 1.54, df = 2 (P = 0.46); I^2 =0.0%							
Test for overall effect: Z = 2.64 (P = 0.0083)							
3 24 months follow-up (12 months post intervention)							
Quattrin 2012	46	-6 (4.4)	50	0.7 (4.2)		100.0 %	-6.70 [-8.42, -4.98]
Subtotal (95% CI)	**46**		**50**			**100.0 %**	**-6.70 [-8.42, -4.98]**
Heterogeneity: not applicable							
Test for overall effect: Z = 7.62 (P < 0.00001)							



(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

Analysis 1.8. Comparison 1 Multicomponent intervention versus control, Outcome 8 Changes in health-related quality of life: DUX 25.

Changes in health-related quality of life: DUX 25

Study	Domain	Intervention median (25th-75th percentile), N	Control median (25th-75th percentile), N	P value
12 months follow-up (8 months post intervention)				
Bocca 2012	Total	5.0 (-1.8; 6.5), 20	-4.5 (-15.3; 4.0), 20	P = 0.04
Bocca 2012	Physical	8.3 (-6.3; 16.7), 20	-4.2 (-12.5; 4.7), 20	P = 0.03
Bocca 2012	Home	-4.2 (-12.5; 4.7), 20	0.0 (-15.0; 10.0), 20	P = ns
Bocca 2012	Emotional	0.0 (-3.6; 3.6), 20	-3.6 (-17.9; 10.7), 20	P = ns
Bocca 2012	Social	1.8 (-9.8; 7.1), 20	-8.9 (-14.3; 1.8), 20	P = ns

Analysis 1.9. Comparison 1 Multicomponent intervention versus control, Outcome 9 Changes in health-related quality of life: CHQ-PF50.

Changes in health-related quality of life: CHQ-PF50

Study	Domain	Intervention median (25th;75th percentile), N	Control median (25th;75th percentile), N	P value
12 months follow-up (8 months post intervention)				
Bocca 2012	Global health Physical functioning	0.0 (-12.5; 20.0), 20 0.0 (-1.4; 12.5), 20	0.0 (-25.0; 0.0), 20 0.0 (0.0; 9.7), 20	P = ns P = ns
Bocca 2012	Role functioning - Emotional/ behaviour Role functioning - physical	0.0 (0.0; 0.0), 20 0.0 (0.0; 0.0), 20	0.0 (0.0; 0.0), 20 0.0 (0.0; 0.0), 20	P = ns P = ns
Bocca 2012	Bodily pain General behaviour	0.0 (-5.0; 20.0), 20 0.0 (0.0; 25.0), 20	0.0 (-17.5; 27.5), 20 0.0 (-22.5; 25.0), 20	P = ns P = ns
Bocca 2012	Behaviour Mental health	4.2 (-9.4; 18.3), 20 0.0 (-5.0; 10.0), 20	-9.6 (-16.7; 6.3), 20 -5.0 (-15.0; 10.0), 20	P = ns P = ns
Bocca 2012	Self-esteem General health	12.5 (-5.2; 29.2), 20 0.0 (-3.3; 15.4), 20	4.2 (-8.3; 12.5), 20 4.2 (-16.0; 17.9), 20	P = ns P = ns
Bocca 2012	Change in health Parental impact - emotional	25.0 (0.0; 31.3), 20 0.0 (-8.3; 8.3), 20	12.5 (0.0; 25.0), 20 -4.2 (-14.6; 8.3), 20	P = ns P = ns

Changes in health-related quality of life: CHQ-PF50 (*Continued*)

Bocca 2012	Parental impact - time Family activities	0.0 (-11.1; 11.1), 20 -4.2 (-13.5; 8.3), 20	0.0 (-11.1; 0.0), 20 0.0 (-8.3; 12.5), 20	P = ns P = ns
Bocca 2012	Family cohesion	0.0 (-15.0; 25.0), 20	0.0 (-25.0; 22.5), 20	P = ns P = ns

Analysis 1.10. Comparison 1 Multicomponent intervention versus control, Outcome 10 Changes in health-related quality of life: PEDsQL physical functioning.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 10 Changes in health-related quality of life: PEDsQL physical functioning

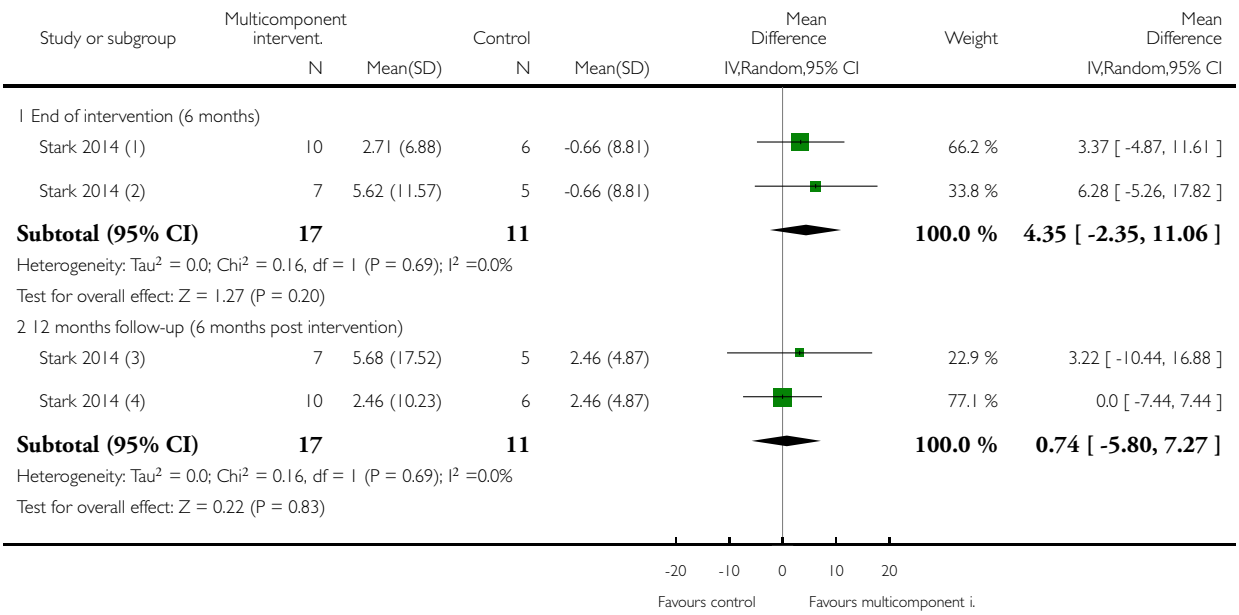
Study or subgroup	Multicomponent intervent. N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 End of intervention (6 months)						
Stark 2011	7	9.5 (13)	10	-1.7 (6.5)		11.20 [0.76, 21.64]
2 12 months follow-up (6 months post intervention)						
Stark 2011	7	13.8 (8.6)	9	-2.7 (5.6)		16.50 [9.15, 23.85]

Analysis 1.11. Comparison 1 Multicomponent intervention versus control, Outcome 11 Changes in health-related quality of life: PEDsQL total score.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 11 Changes in health-related quality of life: PEDsQL total score



(1) LAUNCH clinic only vs control (control n halved) at end of intervention

(2) LAUNCH with home visits vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

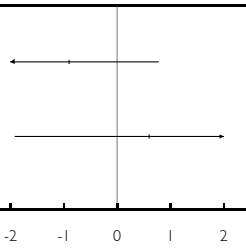
Analysis 1.12. Comparison 1 Multicomponent intervention versus control, Outcome 12 Changes in waist circumference.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 12 Changes in waist circumference

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 End of intervention (6 months)						
Lanigan 2010	33	0.3 (2.4)	25	1.2 (3.7)		-0.90 [-2.57, 0.77]
2 12 months follow-up (8 months post intervention)						
Bocca 2012	32	0.9 (4.6)	25	0.3 (5)		0.60 [-1.93, 3.13]



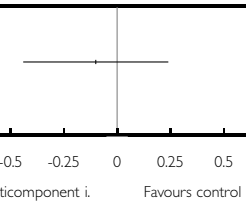
Analysis 1.13. Comparison 1 Multicomponent intervention versus control, Outcome 13 Changes in waist circumference z-score.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 13 Changes in waist circumference z-score

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-0.4 (0.6)	25	-0.3 (0.7)		-0.10 [-0.44, 0.24]



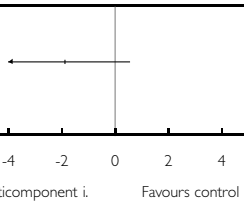
Analysis 1.14. Comparison 1 Multicomponent intervention versus control, Outcome 14 Changes in hip circumference.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 14 Changes in hip circumference

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	0.4 (4.5)	25	2.3 (4.9)		-1.90 [-4.37, 0.57]



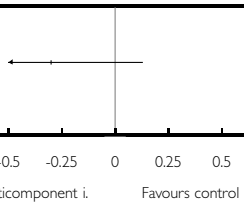
Analysis 1.15. Comparison 1 Multicomponent intervention versus control, Outcome 15 Changes in hip circumference z-score.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 15 Changes in hip circumference z-score

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-0.5 (0.7)	25	-0.2 (0.9)		-0.30 [-0.73, 0.13]



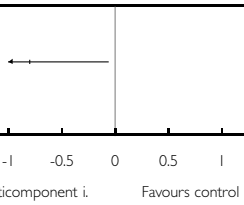
Analysis 1.16. Comparison 1 Multicomponent intervention versus control, Outcome 16 Changes in upper arm circumference.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 16 Changes in upper arm circumference

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-0.3 (1.3)	25	0.5 (1.5)		-0.80 [-1.54, -0.06]



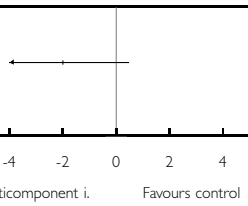
Analysis 1.17. Comparison 1 Multicomponent intervention versus control, Outcome 17 Changes in per cent body fat.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 17 Changes in per cent body fat

Study or subgroup	Multicomponent intervent. N	Mean(SD)[%]	Control N	Mean(SD)[%]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-1.7 (4.5)	25	0.3 (4.9)		-2.00 [-4.47, 0.47]



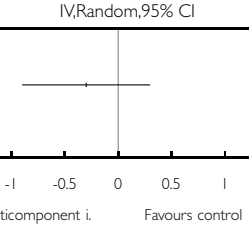
Analysis 1.18. Comparison 1 Multicomponent intervention versus control, Outcome 18 Changes in fat-free mass.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 18 Changes in fat-free mass

Study or subgroup	Multicomponent intervent. N	Mean(SD)[kg]	Control N	Mean(SD)[kg]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	1.8 (1.3)	25	2.1 (1)		-0.30 [-0.90, 0.30]



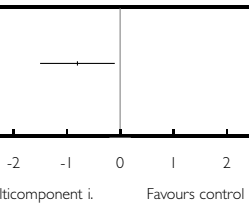
Analysis 1.19. Comparison 1 Multicomponent intervention versus control, Outcome 19 Changes in visceral fat.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 19 Changes in visceral fat

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-0.7 (1.5)	25	0.1 (1.2)		-0.80 [-1.50, -0.10]



Analysis 1.20. Comparison 1 Multicomponent intervention versus control, Outcome 20 Changes in subcutaneous fat.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 20 Changes in subcutaneous fat

Study or subgroup	Multicomponent intervent. N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 12 months follow-up (8 months post intervention)						
Bocca 2012	32	-0.2 (0.4)	25	0 (0.4)		-0.20 [-0.41, 0.01]

Analysis 1.21. Comparison 1 Multicomponent intervention versus control, Outcome 21 Changes in outdoor active play.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 21 Changes in outdoor active play

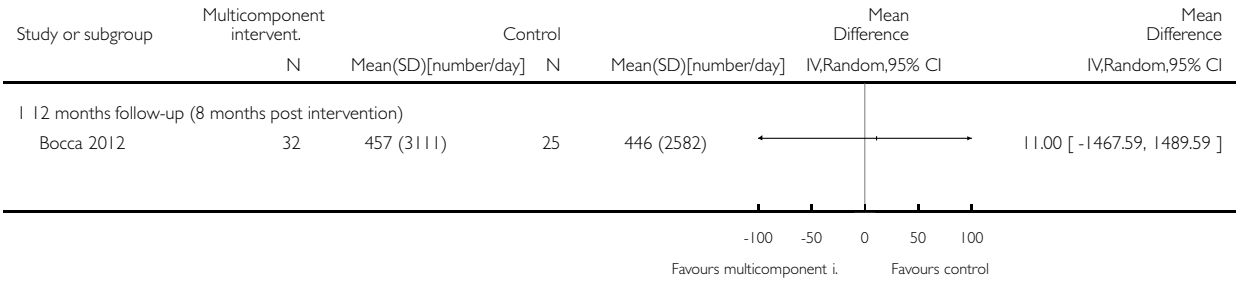
Study or subgroup	Multicomponent intervent. N	Mean(SD)[hours/day]	Control N	Mean(SD)[hours/day]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 End of intervention (12 months)						
Taveras 2011	253	0.06 (1.6)	192	0.2 (1.8)		-0.14 [-0.46, 0.18]

Analysis 1.22. Comparison 1 Multicomponent intervention versus control, Outcome 22 Changes in steps.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 22 Changes in steps

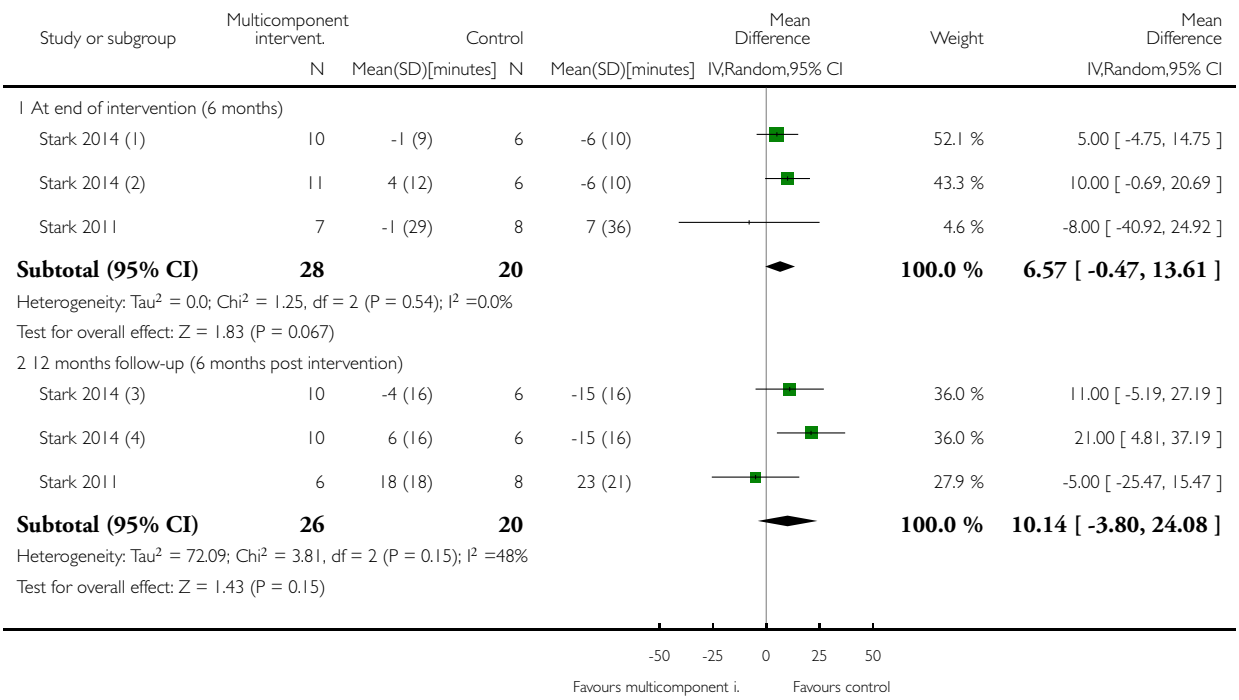


Analysis 1.23. Comparison 1 Multicomponent intervention versus control, Outcome 23 Changes in physical activity, moderate.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 23 Changes in physical activity, moderate



(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

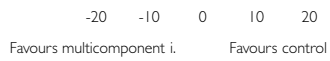
Analysis 1.24. Comparison 1 Multicomponent intervention versus control, Outcome 24 Changes in physical activity, vigorous.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 24 Changes in physical activity, vigorous

Study or subgroup	Multicomponent intervent. N	Mean(SD)[minutes]	Control N	Mean(SD)[minutes]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 End of intervention (6 months)							
Stark 2014 (1)	10	4 (6)	6	1 (6)		45.1 %	3.00 [-3.07, 9.07]
Stark 2014 (2)	11	4 (9)	6	1 (6)		32.4 %	3.00 [-4.16, 10.16]
Stark 2011	7	3 (8)	8	1 (9)		22.5 %	2.00 [-6.60, 10.60]
Subtotal (95% CI)	**28**		**20**			**100.0 %**	**2.78 [-1.30, 6.85]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.04$, df = 2 (P = 0.98); $I^2 = 0.0\%$							
Test for overall effect: Z = 1.33 (P = 0.18)							
2 12 months follow-up (6 months post intervention)							
Stark 2014 (3)	10	4 (10)	6	-4 (8)		26.7 %	8.00 [-0.91, 16.91]
Stark 2014 (4)	11	7 (8)	6	-4 (8)		33.4 %	11.00 [3.04, 18.96]
Stark 2011	6	7 (8)	8	3 (5)		39.9 %	4.00 [-3.28, 11.28]
Subtotal (95% CI)	**27**		**20**			**100.0 %**	**7.40 [2.81, 12.00]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.64$, df = 2 (P = 0.44); $I^2 = 0.0\%$							
Test for overall effect: Z = 3.16 (P = 0.0016)							



(1) LAUNCH with home visits vs control (control n halved) at end of intervention

(2) LAUNCH clinic only vs control (control n halved) at end of intervention

(3) LAUNCH with home visits vs control (control n halved) at 12 months follow-up

(4) LAUNCH clinic only vs control (control n halved) at 12 months follow-up

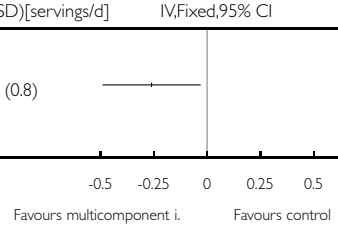
Analysis 1.25. Comparison 1 Multicomponent intervention versus control, Outcome 25 Changes in sugar-sweetened drinks.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 25 Changes in sugar-sweetened drinks

Study or subgroup	Multicomponent intervent. N	Mean(SD)[servings/d]	Control N	Mean(SD)[servings/d]	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 End of intervention (12 months)						
Taveras 2011	253	-0.59 (1.6)	192	-0.33 (0.8)		-0.26 [-0.49, -0.03]



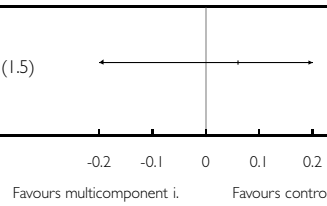
Analysis 1.26. Comparison 1 Multicomponent intervention versus control, Outcome 26 Changes in fruit and vegetable intake.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 26 Changes in fruit and vegetable intake

Study or subgroup	Multicomponent intervent. N	Mean(SD)[servings/d]	Control N	Mean(SD)[servings/d]	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 End of intervention (12 months)						
Taveras 2011	253	0.22 (1.4)	192	0.16 (1.5)		0.06 [-0.21, 0.33]



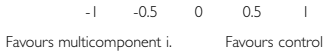
Analysis 1.27. Comparison 1 Multicomponent intervention versus control, Outcome 27 Changes in TV and video viewing.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 1 Multicomponent intervention versus control

Outcome: 27 Changes in TV and video viewing

Study or subgroup	Multicomponent intervent. N	Mean(SD)[hours/day]	Control N	Mean(SD)[hours/day]	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 End of intervention (12 months)						
Taveras 2011	253	-0.53 (1.4)	192	-0.07 (1.2)		-0.46 [-0.70, -0.22]



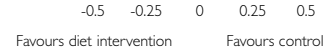
Analysis 2.1. Comparison 2 Diet intervention versus control, Outcome 1 Changes in BMI z score.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 2 Diet intervention versus control

Outcome: 1 Changes in BMI z score

Study or subgroup	Diet intervention N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 Dairy rich: end of intervention (6 months)						
Kelishadi 2009	39	-0.6 (0.01)	20	-0.5 (0.01)		-0.10 [-0.11, -0.09]
2 Energy restricted: end of intervention (6 months)						
Kelishadi 2009	38	-0.6 (0.01)	19	-0.5 (0.01)		-0.10 [-0.11, -0.09]
3 Dairy rich: 12 months follow-up (6 months post intervention)						
Kelishadi 2009	39	-0.4 (0.01)	18	-0.2 (0.01)		-0.20 [-0.21, -0.19]
4 Energy restricted: 12 months follow-up (6 months post intervention)						
Kelishadi 2009	35	-0.2 (0.01)	17	-0.2 (0.01)		0.0 [-0.01, 0.01]
5 Dairy rich: 24 months follow-up (18 months post intervention)						
Kelishadi 2009	36	-0.3 (0.01)	17	0.3 (0.01)		-0.60 [-0.61, -0.59]
6 Energy restricted: 24 months follow-up (18 months post intervention)						
Kelishadi 2009	33	0.4 (0.01)	16	0.3 (0.01)		0.10 [0.09, 0.11]



(*Continued* . . .)

(. . . *Continued*)

Study or subgroup	Diet intervention N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
7 Dairy rich: 36 months follow-up (30 months post intervention)						
Kelishadi 2009	36	-0.1 (0.004)	16	0.6 (0.02)		-0.70 [-0.71, -0.69]
8 Energy restricted: 36 months follow-up (30 months post intervention)						
Kelishadi 2009	31	0.7 (0.01)	16	0.6 (0.02)		0.10 [0.09, 0.11]

Analysis 2.2. Comparison 2 Diet intervention versus control, Outcome 2 Changes in waist circumference.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 2 Diet intervention versus control

Outcome: 2 Changes in waist circumference

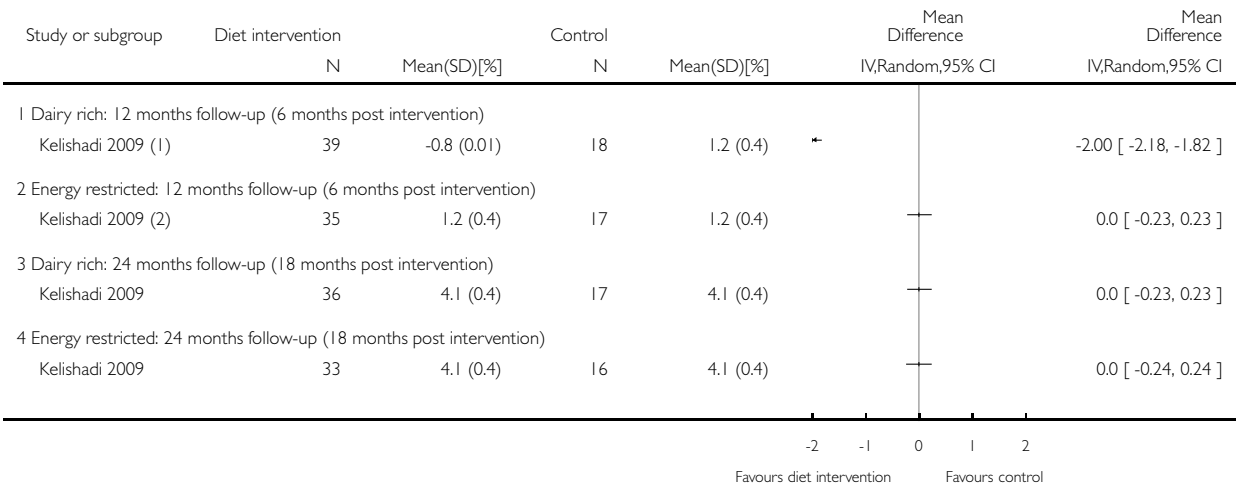
Study or subgroup	Diet intervention N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
1 Dairy rich: end of intervention (6 months)						
Kelishadi 2009	39	-2 (0.1)	20	-1.7 (0.2)		-0.30 [-0.39, -0.21]
2 Energy restricted: end of intervention (6 months)						
Kelishadi 2009	38	-2.5 (0.2)	19	-1.7 (0.2)		-0.80 [-0.91, -0.69]
3 Dairy rich: 12 months follow-up (6 months post intervention)						
Kelishadi 2009	39	-1.2 (0.1)	18	2 (0.2)		-3.20 [-3.30, -3.10]
4 Energy restricted: 12 months follow-up (6 months post intervention)						
Kelishadi 2009	35	1.8 (0.2)	17	2 (0.2)		-0.20 [-0.32, -0.08]
5 Dairy rich: 24 months follow-up (18 months post intervention)						
Kelishadi 2009	36	2.5 (0.2)	17	3.5 (0.2)		-1.00 [-1.12, -0.88]
6 Energy restricted: 24 months follow-up (18 months post intervention)						
Kelishadi 2009	33	3 (0.2)	16	3.5 (0.2)		-0.50 [-0.62, -0.38]
7 Dairy rich: 36 months follow-up (30 months post intervention)						
Kelishadi 2009	36	4.1 (0.3)	16	4.8 (0.2)		-0.70 [-0.84, -0.56]
8 Energy restricted: 36 months follow-up (30 months post intervention)						
Kelishadi 2009	31	5.2 (0.4)	16	4.8 (0.2)		0.40 [0.23, 0.57]

Analysis 2.3. Comparison 2 Diet intervention versus control, Outcome 3 Changes in per cent body fat.

Review: Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years

Comparison: 2 Diet intervention versus control

Outcome: 3 Changes in per cent body fat



(1) At 12 months: SD for dairy rich diet and control group imputed from values at 24 months

(2) At 12 months: SDs for diary diet and control group imputed from values at 24 months

ADDITIONAL TABLES

Table 1. Overview of study populations

	Intervention(s) and comparator(s)	Sample size[a]	Screened/ eligible [N]	Randomised [N]	ITT [N]	Analysed [N]	Finishing study [N]	Randomised finishing study [%]	Follow-up time[b]
Stark 2014	I1: LAUNCH home visits	"Because of the small sample size, we	-/237	15	10	10	7	47	6 months/ 12 months

Table 1. Overview of study populations (*Continued*)

		were not powered to compare the two LAUNCH groups“							
	I2: LAUNCH clinic visits			14	11	11	10	71	
	C: enhanced usual care			13	12	12	11	85	
	total:			42	33	33	28	67	
Quattrin 2012	I: family-based intervention	In a mixed-effect model a sample of 108 participants was required to have at least 85% power to detect a treatment difference of ≥ 8.7% (change in child per cent over BMI) between the intervention	171/147	52	46	46	30	58	12 months/ 24 months
	C: information control			53	50	50	40	76	
	total:			105	96	96	70	73	
Bocca 2012	I: multidisciplinary programme	-	78/75	40	-	17	17	43	16 weeks/3 years
	C: usual care			35	-	12	12	34	
	total:			75	-	29	29	39	

Table 1. Overview of study populations (*Continued*)

Taveras 2011	I: High Five for Kids: behavioural intervention	-	1486 attempted contact/ 361 contacted, pre-eligible, willing	271 (5 clusters)	-	253	253	93	12 months (end of intense phase; 2-year data not reported)
	C: usual care		1007 attempted contact/ 267 contacted, pre-eligible, willing	204 (5 clusters)	-	192	192	94	
	total:			475		445	445	94	
Stark 2011	I: LAUNCH	-	4079/56	8	-	7 (month 6 and 12)	7	88	6 months/ 12 months
	C: enhanced standard care			10	-	10 (month 6) 9 (month 12)	9	90	
	total:			18	-	16	16	89	
Lanigan 2010	I: Trim Tots multi-component intervention	-	105/105	49	49	49	21	43	6 months/2 years (6-month follow-up reported only)
	C: wait-list control			39	39	39	21	54	
	total:			88	88	88	42	48	
Kelishadi 2009	I1: dairy-rich diet	30 per group	-	40	-	-	36	90	6 months/3 years
	I2: energy-restricted diet			40	-	-	31	78	
	C: control			40	-	-	32	80	
	total:			120			99	83	

Table 1. Overview of study populations (*Continued*)

Grand total	***All interventions***				***529***				***412***		
	All c omparators				***394***				***317***		
	All interventions and c omparators				***923***				***729***		

[a] According to power calculation in study publication or report.
[b] Duration of intervention and/or follow-up under randomised conditions until end of study.
- denotes not reported
C: comparator; I: intervention; ITT: intention-to-treat; LAUNCH: Learning about Activity and Understanding Nutrition for Child Health; N/A: not applicable

APPENDICES

Appendix 1. Search strategies

Cochrane Library
Part I: Obesity
1. [mh Ôbesity]
2. [mh ^"Obesity, Morbid"]
3. [mh ^"Obesity, Abdominal"]
4. [mh ^"Pediatric Obesity"]
5. [mh Ôverweight]
6. [mh ^"Weight Loss"]
7. (adipos* or obes*):ti,ab
8. (overweight* or ("over" next weight*)):ti,ab
9. ("weight" near/1 (reduc* or los* or control* or manage*)):ti,ab
10. {or #1-#9}
Part II: Intervention
11. [mh "Behavior Therapy"]
12. [mh "Counseling"]
13. [mh ^"Family Therapy"]
14. [mh ^"Social Support"]
15. [mh ^"Program Evaluation"]
16. [mh "Exercise"]

(*Continued*)

17. [mh "Exercise Therapy"]
18. [mh "Physical Education and Training"]
19. [mh "Exercise Movement Techniques"]
20. [mh ^"Motor Activity"]
21. [mh Diet]
22. [mh "Diet Therapy"]
23. [mh ^"Patient Education as Topic"]
24. [mh ^"Health Education"]
25. [mh "Health Behavior"]
26. [mh "Health Promotion"]
27. [mh ^"School Health Services"]
28. [mh ^"School Nursing"]
29. [mh ^"Life style"]
30. (("obesity" near/4 "intervention") or "program" or "programme" or "camp" or "camps"):ti,ab
31. ("lifestyle" or "life style"):ti,ab
32. exercis*:ti,ab
33. (physic* next (activ* or fit*)):ti,ab
34. (walk* or jog* or swim* or ("weight" next lift*) or danc* or "aerobics"):ti,ab
35. ((physic* or strength* or resist* or "circuit" or "weight" or aerob* or "cross" or "endurance" or structur*) near/4 train*):ti,ab
36. ("behavioral" or "behavioural" or (("behavior" or "behaviour") next "modification") or psychoth* or "psychosocial"):ti,ab
37. (("group" or "family" or cognit* or behav*) next therap*):ti,ab
38. (counseling or counselling):ti,ab
39. educat*:ti,ab
40. (("parent" or "parents" or "family") next ("based" or "focused" or "directed" or "centered" or "only" or "led")):ti,ab
41. (diet* or "healthy nutrition" or (nutrition* next ("knowledge" or educat* or therap* or program* or intervention*))):ti,ab
42. {or #11-#41}

Part III: Part I + Part II and additional MeSH/subheading combination

43. #10 and #42
44. [mh Ôbesity] or [mh ^"Obesity, Morbid"] or [mh Ôverweight]
45. [mh /DH,PC,RH,TH,PX]*[diet therapy or prevention & control or rehabilitation or therapy or psychology]*
46. #44 and #45
47. #43 or #46

Part IV: Population [adapted from Leclercq 2013*]*

48. [mh Âdolescent]
49. [mh Child]
50. [mh Înfant]
51. [mh ^Pediatrics]
52. "minors":ti,ab
53. ("boy" or "boys" or "boyhood"):ti,ab
54. girl*:ti,ab
55. ("kid" or "kids"):ti,ab
56. infant*:ti,ab
57. ("baby" or "babies"):ti,ab
58. ("toddler" or "toddlers"):ti,ab
59. ("child" or "childs" or children* or childhood* or childcare* or schoolchild*):ti,ab
60. adolescen*:ti,ab
61. juvenil*:ti,ab
62. youth*:ti,ab
63. (teen* or preteen*):ti,ab

(*Continued*)

64. (underage* or (”under“ next age*)):ti,ab
65. pubescen*:ti,ab
66. (paediatric* or pediatric*):ti,ab
67. {or #48-#66}
Part V: Part III AND IV and additional MeSH/subheading combination
68. #47 and #67
69. [mh ^”Pediatric Obesity“]
70. [mh /DH,PC,RH,TH,PX]
71. #69 and #70
72. #68 or #71

MEDLINE (Ovid SP)

Part I: Obesity
1. Obesity/
2. Obesity, Morbid/
3. Obesity, Abdominal/
4. Pediatric Obesity/
5. Overweight/
6. Weight Loss/
7. (adipos* or obes*).tw.
8. (overweight* or over weight*).tw.
9. (weight adj1 (reduc* or los* or control* or manage*)).tw.
10. or/1-9
Part II: Intervention
11. exp Behavior Therapy/
12. exp Counseling/
13. Family Therapy/
14. Social Support/
15. Program Evaluation/
16. exp Exercise/
17. exp Exercise Therapy/
18. exp ”Physical Education and Training“/
19. exp Exercise Movement Techniques/
20. Motor Activity/
21. exp Diet/
22. exp Diet Therapy/
23. Patient Education as Topic/
24. Health Education/
25. exp Health Behavior/
26. exp Health Promotion/
27. School Health Services/
28. School Nursing/
29. Life style/
30. ((obesity adj3 intervention) or program or programme or camp?).tw
31. (lifestyle or life style).tw.
32. exercis*.tw.
33. (physic* adj (activ* or fit*)).tw.
34. (walk* or jog* or swim* or weight lift* or danc* or aerobics).tw

(*Continued*)

35. ((physic* or strength* or resist* or circuit or weight or aerob* or cross or endurance or structur*) adj3 train*).tw
36. (behavio?ral or behavio?r modification or psychoth* or psychosocial).tw
37. ((group or family or cognit* or behav*) adj therap*).tw.
38. counsel?ing.tw.
39. educat*.tw.
40. ((parent? or family) adj (based or focused or directed or centered or only or led)).tw
41. (diet* or healthy nutrition or (nutrition* adj (knowledge or educat* or therap* or program* or intervention*))).tw
42. or/11-41

Part III: Part I + Part II and additional MeSH/subheading combination

43. 10 and 42
44. Obesity/ or Obesity, Morbid/ or Overweight/ or Weight Loss/
45. diet therapy.fs. or prevention & control.fs. or rehabilitation.fs. or therapy.fs. or psychology.fs
46. 44 and 45
47. 43 or 46

Part IV: Population [adapted from Leclercq 2013*]*

48. Adolescent/
49. exp Child/
50. Infant/
51. Pediatrics/
52. minors.tw.
53. (boy or boys or boyhood).tw.
54. girl*.tw.
55. infant*.tw.
56. (baby or babies).tw.
57. toddler?.tw.
58. (kid or kids).tw.
59. (child or childs or children* or childhood* or childcare* or schoolchild*).tw
60. adolescen*.tw.
61. juvenil*.tw.
62. youth*.tw.
63. (teen* or preteen*).tw.
64. (underage* or under age*).tw.
65. pubescen*.tw.
66. p?ediatric*.tw.
67. or/48-66

Part V: Part III AND IV and additional MeSH/subheading combination

68. 47 and 67
69. Pediatric Obesity/
70. diet therapy.fs. or prevention & control.fs. or rehabilitation.fs. or therapy.fs. or psychology.fs
71. 69 and 70
72. 68 or 71

Part VI: Study filter [Cochrane Handbook 2008 RCT filter - sensitivity and precision maximizing version]

73. randomized controlled trial.pt.
74. controlled clinical trial.pt.
75. randomi?ed.ab.
76. placebo.ab.
77. clinical trials as topic/
78. randomly.ab.
79. trial.ti.

(*Continued*)

80. or/73-79
81. exp animals/ not humans/
82. 80 not 81
Part VII: Part V + Part VI
83. 72 and 82

EMBASE (Ovid SP)

Part I: Obesity
1. obesity/
2. morbid obesity/
3. abdominal obesity/
4. childhood obesity/
5. weight reduction/
6. weight control/
7. (adipos* or obes*).tw.
8. (overweight* or over weight*).tw.
9. (weight adj1 (reduc* or los* or control* or manage*)).tw.
10. or/1-9
Part II: Intervention
11. behavior therapy/
12. cognitive therapy/
13. exp counseling/
14. family therapy/
15. social support/
16. exp program evaluation/
17. exp exercise/
18. exp physical education/
19. exp physical activity/
20. exp motor activity/
21. training/
22. exp diet/
23. exp diet therapy/
24. nutritional health/
25. child nutrition/
26. feeding behavior/
27. patient education/
28. health promotion/
29. health literacy/
30. nutrition education/
31. health education/
32. school health education/
33. school health service/
34. lifestyle/
35. lifestyle modification/
36. ((obesity adj3 intervention) or program or programme or camp?).tw
37. (lifestyle or life style).tw.
38. exercis*.tw.
39. (physic* adj (activ* or fit*)).tw.

(*Continued*)

40. (walk* or jog* or swim* or weight lift* or danc* or aerobics).tw
41. ((physic* or strength* or resist* or circuit or weight or aerob* or cross or endurance or structur*) adj3 train*).tw
42. (behavio?ral or behavio?r modification or psychoth* or psychosocial).tw
43. ((group or family or cognit* or behav*) adj therap*).tw.
44. counsel?ing.tw.
45. educat*.tw.
46. ((parent? or family) adj (based or focused or directed or centered or only or led)).tw
47. (diet* or healthy nutrition or (nutrition* adj (knowledge or educat* or therap* or program* or intervention*))).tw
48. or/11-47

Part III: Part I + Part II and additional MeSH/subheading combination

49. 10 and 48
50. obesity/ or morbid obesity/
51. pc.fs or rh.fs or th.fs. *[prevention.fs. or rehabilitation.fs. or therapy.fs.]*
52. 50 and 51
53. 49 or 52

Part IV: Population [adapted from Leclercq 2013*]*

54. juvenile/
55. adolescent/
56. child/
57. infant/
58. baby/
59. toddler/
60. preschool child/
61. school child/
62. pediatrics/
63. minors.tw.
64. (boy or boys or boyhood).tw.
65. girl*.tw.
66. infant*.tw.
67. (baby or babies).tw.
68. toddler?.tw.
69. (kid or kids).tw.
70. (child or childs or children* or childhood* or childcare* or schoolchild*).tw
71. adolescen*.tw.
72. juvenil*.tw.
73. youth*.tw.
74. (teen* or preteen*).tw.
75. (underage* or under age*).tw.
76. pubescen*.tw.
77. p?ediatric*.tw.
78. or/54-77

Part V: Part III AND IV and additional MeSH/subheading combination

79. 53 and 78
80. childhood obesity/
81. pc.fs or rh.fs or th.fs. *[prevention.fs. or rehabilitation.fs. or therapy.fs.]*
82. 80 and 81
83. 79 or 82

Part VI: Study filter [Wong 2006a*filter - SDSSGS version]*

84. random*.tw. or clinical trial*.mp. or exp treatment outcome/

(*Continued*)

Part VII: Part V + Part VI
85. 83 and 84

PsycINFO (Ovid SP)

Part I: Obesity
1. exp Overweight
2. (adipos* or obes*).tw.
3. (overweight* or over weight*).tw.
4. or/1-3
Part II: Intervention
5. Weight Control/
6. Weight Loss/
7. Aerobic Exercise/
8. Diets/
9. exp Exercise/
10. Movement Therapy/
11. Dance Therapy/
12. exp Physical Activity/
13. Physical Fitness/
14. Health Behavior/
15. Health Promotion/
16. Health Knowledge/
17. Health Literacy/
18. Health Education/
19. Client Education/
20. Lifestyle/
21. Physical Education/
22. exp Program Evaluation/
23. Educational Programs/
24. Educational Therapy/
25. exp Program Development/
26. School Based Intervention/
27. School Counseling/
28. Counseling/
29. Group Counseling/
30. Family Therapy/
31. Support Groups/
32. Social Support/
33. School Counselors/
34. exp Behavior Modification/
35. Cognitive Behavior Therapy/
36. Cognitive Therapy/
37. ((obesity adj3 intervention) or program or programme or camp?).tw
38. (lifestyle or life style).tw.
39. exercis*.tw.
40. (physic* adj (activ* or fit*)).tw.
41. (walk* or jog* or swim* or weight lift* or danc* or aerobics).tw
42. ((physic* or strength* or resist* or circuit or weight or aerob* or cross or endurance or structur*) adj3 train*).tw

(*Continued*)

43. (behavio?ral or behavio?r modification or psychoth* or psychosocial).tw
44. ((group or family or cognit* or behav*) adj therap*).tw.
45. counsel?ing.tw.
46. educat*.tw.
47. ((parent? or family) adj (based or focused or directed or centered or only or led)).tw
48. (diet* or healthy nutrition or (nutrition* adj (knowledge or educat* or therap* or program* or intervention*))).tw
49. or/5-48

Part III: Part I + Part II

50. 4 and 49

Part IV: Population [adapted from Leclercq 2013*]*

51. minors.tw.
52. (boy or boys or boyhood).tw.
53. girl*.tw.
54. infant*.tw.
55. (baby or babies).tw.
56. toddler?.tw.
57. (kid or kids).tw.
58. (child or childs or children* or childhood* or childcare* or schoolchild*).tw
59. adolescen*.tw.
60. juvenil*.tw.
61. youth*.tw.
62. (teen* or preteen*).tw.
63. (underage* or under age*).tw.
64. pubescen*.tw.
65. p?ediatric*.tw.
66. or/51-65

Part V: Part III AND IV and additional MeSH/subheading combination

67. 50 and 66

Part VI: Study filter [Eady 2008*filter - BS version]*

68. control*.tw. OR random*.tw. OR exp Treatment/

Part VII: Part V + Part VI

69. 67 and 68

CINAHL (EBSCOhost)

Part I: Obesity

S1. MH "Obesity+"
S2. TX (adipos* or obes*)
S3. TX (overweight* or "over weight*")
S4. S1 OR S2 OR S3

Part II: Intervention

S5. MH "Weight Loss"
S6. MH "Behavior Modification+"
S7. MH "Counseling"
S8. MH "Family Therapy"
S9. MH "Support, Psychosocial"
S10.MH "Support Groups"
S11.MH "Program Evaluation"
S12.MH "Program Implementation"
S13.MH "Exercise+"

(*Continued*)

S14.MH "Sports+"
S15.MH "Therapeutic Exercise+"
S16.MH "Physical Fitness"
S17.MH "Physical Education and Training+"
S18.MH "Health Education+"
S19.MH "Diet+"
S20.MH "Diet Therapy+"
S21.MH "Health Behavior"
S22.MH "Eating Behavior"
S23.MH "Health Promotion"
S24.MH "School Health Services+"
S25.MH "Life style changes"
S26.MH "Life style"
S27.TX (weight N1 (reduc* or los* or control* or manage*))
S28.TX ((obesity N3 intervention) OR program OR programme OR camp#)
S29.TX (lifestyle or "life style")
S30.TX exercis*
S31.TX (physic* N1 (activ* or fit*))
S32.TX (walk* or jog* or swim* or weight lift* or danc* or aerobics)
S33.TX ((physic* or strength* or resist* or circuit or weight or aerob* or cross or endurance or structur*) N3 train*)
S34.TX (behavio#ral or behavio#r modification or psychoth* or psychosocial)
S35.TX ((group or family or cognit* or behav*) N1 therap*)
S36.TX counsel#ing
S37.TX educat*
S38.TX ((parent# or family) N1 (based or focused or directed or centered or only or led))
S39.TX (diet* or "healthy nutrition" or (nutrition* N1 (knowledge or educat* or therap* or program* or intervention*)))
S40.S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39
Part III: Part I + Part II and additional MeSH/subheading combination
S41.S4 AND S40
S42.(MH "Obesity+/DH/ED/PC/PF/RH/TH") [diet therapy or education or prevention & control or psychosocial factors or rehabilitation or therapy]
S43.S41 OR S42
Part IV: Population [based on Leclercq 2013*]*
S44.MH "Adolescence"
S45.MH "Child+"
S46.MH "Infant"
S47.MH "Pediatrics"
S48.TX minors
S49.TX (boy OR boys OR boyhood)
S50.TX girl*
S51.TX infant*
S52.TX (baby OR babies)
S53.TX toddler#
S54.TX (kid OR kids)
S55.TX (child OR childs OR children* OR childhood* OR childcare* OR schoolchild*)
S56.TX adolescen*
S57.TX juvenil*

(*Continued*)

S58.TX youth*
S59.TX (teen* or preteen*)
S60.TX (underage* or under age*)
S61.TX pubescen*
S62.TX (paediatric* OR pediatric*)
S63.S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S62
Part V: Part III AND IV and additional MeSH/subheading combination
S64.S43 AND S63
S65.(MH "Pediatric Obesity/DH/ED/PC/PF/RH/TH") [diet therapy or education or prevention & control or psychosocial factors or rehabilitation or therapy]
S66.S64 OR S65
Part VI: Study filter [Wong 2006b*filter - SDSSGS version]*
S67.MH "treatment outcomes+" OR MH "experimental studies+" or random*
Part VII: Part V + Part VI
S68.S66 AND S67

LILACS (IAHx)

((((MH:"Obesity" OR MH:"Obesity, Morbid" OR MH:"Obesity, Abdominal" OR MH:"Pediatric Obesity" OR MH:"Overweight" OR adipos$ OR obes$ OR overweight$ OR "over weight" OR sobrepes$ OR "exceso de peso" OR "excesso de peso") AND (MH:"Weight Loss" OR MH:"Exercise" OR MH:"Exercise Therapy" OR MH:"Physical Education and Training" OR MH:"Exercise Movement Techniques" OR MH:"Weight Reduction Programs" OR MH:"Motor Activity" OR MH:"Behavior Therapy" OR MH:"Counseling" OR MH:"Family Therapy" OR MH:"Social Support" OR MH:"Program Evaluation" OR MH:"Diet" OR MH:"Diet Therapy" OR MH:"Patient Education as Topic" OR MH:"Health Education" OR MH:"Health Behavior" OR MH:"Health Promotion" OR MH:"Weight Reduction Programs" OR MH:"School Health Services" OR MH:"Life style" OR exerci$ OR ejerci$ OR ((physic$ OR fisic$) AND (activ$ OR ativid$ OR fit$ OR educac$ OR entrenam$ OR treinam$)) OR ((physic$ OR fisic$ OR strength$ OR forca OR fuerza OR resist$ OR circuit$ OR weight OR aerob$ OR endurance OR structur$ OR estructur$) AND train$ OR treina$ OR entrena$) OR program$ OR "estilo de vida" OR padres OR pais OR familia OR familias OR familiar OR terapia OR orienta$ OR educa$ OR diet$ OR nutric$ OR "weight reduction" OR "weight loss" OR "weight control" OR "control de peso")) OR (MH:"Obesity/diet therapy" OR MH:"Obesity, Morbid/diet therapy" OR MH:"Overweight/diet therapy" OR MH:"Obesity/prevention & control" OR MH:"Obesity, Morbid/prevention & control " OR MH:"Overweight/prevention & control" OR MH:"Obesity/rehabilitation" OR MH:"Obesity, Morbid/rehabilitation" OR MH:"Overweight/rehabilitation" OR MH:"Obesity/therapy" OR MH:"Obesity, Morbid/therapy" OR MH:"Overweight/therapy" OR MH:"Obesity/psychology" OR MH:"Obesity, Morbid/psychology" OR MH:"Overweight/psychology")) AND (MH:"Adolescent" OR MH:"Child" OR MH:"Pediatrics" OR MH:"Infant" OR minors OR boy OR boys OR girl$ OR kid OR kids OR child OR childs OR children$ OR childhood$ OR childcare$ OR schoolchild$ OR escolar$ OR adolescen$ OR preadolescen$ OR juvenil$ OR juventud$ OR youth$ OR teen$ OR preteen$ OR underage$ OR pubescen$ OR paediatri$ OR pediatri$ OR joven$ OR jovem$ OR niños OR niñas OR crianca$ OR menin$ OR "menor de edad" OR "menores de edad" OR "menor de idade" OR "menores de idade")) OR MH:"Pediatric Obesity/diet therapy" OR MH:"Pediatric Obesity/prevention & control" OR MH:"Pediatric Obesity/rehabilitation" OR MH:"Pediatric Obesity/therapy" OR MH:"Pediatric Obesity/psychology"
[activated filter "Controlled Clinical Trial"]

ICTRP Search Portal (Advanced search)

[activated "Search for clinical trials in children"]:
in Title: obes* OR overweight*
OR
in Condition: obes* OR overweight*
Recruitment Status: ALL

(*Continued*)

ClinicalTrials.gov (Advanced search)
Conditions: obese OR overweight OR obesity **Study type:** Interventional Studies **Age Group:** Child (birth-17)

Appendix 2. Description of interventions

	Intervention(s)	**Comparator(s)**
Stark 2014	I1: **LAUNCH and home visits:** 6 months, 18 sessions, intensive and maintenance phases. Focus on group-based clinic sessions and individual home visits targeting lifestyle behaviour modification	**Enhanced usual care:** paediatrician counselling based on published dietary and physical-activity recommendations. 1 session
	I2: **LAUNCH and clinic visits:** identical to LAUNCH and home visits minus the home visits	
Quattrin 2012	**Family-based intervention:** diet and physical-activity goals and behavioural/parenting intervention over 12 months. 13 sessions and 10 phone calls in between sessions	**Information control:**diet and physical-activity goals over 12 months, 13 sessions and 10 phone calls in between sessions
Bocca 2012	**Multidisciplinary treatment programme:** 25 sessions over 16 weeks of dietary advice, lifestyle activity, and psychological counselling	**Usual care:** 3 sessions with paediatrician over 16 weeks
Taveras 2011	**High Five for Kids:** behavioural intervention using motivational interviewing face-to-face and by telephone, educational modules, behavioural goals. 2-year intervention (12 months intensive, 12 months maintenance)	**Usual care control:** well-child care visits and follow-up appointments for weight checks as standard care over 12 months
Stark 2011	**LAUNCH:** 12 weekly parent and child concurrent group sessions in clinic, 12 fortnightly sessions alternating between group clinic and home. Dietary education, physical activity, and parenting skills	**Enhanced standard care:** one 45-min paediatrician visit focusing on BMI, diet, and activity recommendations
Lanigan 2010	**Trim Tots:** multicomponent intervention, twice weekly sessions for 3 months, weekly for 3 months	**Wait-list control:** no details
Kelishadi 2009	I1: **Dairy-rich diet:** 6x monthly family-centred healthy lifestyle education sessions + increased-calcium diet	**Control:** 6x monthly family-centred healthy lifestyle education sessions

(*Continued*)

	I2: **Energy-restricted diet:** 6x monthly family-centred healthy lifestyle education sessions + reduced-calorie diet	

BMI: body mass index; I: intervention; LAUNCH: Learning about Activity and Understanding Nutrition for Child Health

Appendix 3. Baseline characteristics (I)

	Intervention(s) and comparator (s)	Duration of intervention (duration of follow-up)	Description of participants	Study period [year to year]	Country	Setting	Ethnic groups [%]	Socioeconomic status
Stark 2014	I1: LAUNCH home visits	6 months (12 months)	Age 2 to 5 years, BMI ≥ 95th percentile but < 100% above the mean BMI, parent with BMI ≥ 25	2009 to 2011	USA	Outpatients	White: 90	Hollingshead score: 49.8 (8.5) Family income, %: Under USD 50,000: 11; USD 50,000 to 99,999: 33; ≥ USD 100,000: 56
	I2: LAUNCH clinic visits						White: 91	Hollingshead score: 43.3 (13.0) Family income, %: Under USD 50,000: 18; USD 50,000 to 99,999: 55; ≥ USD 100,000: 27
	C: enhanced usual care						White: 75	Hollingshead score: 45.8 (8.4) Family income, %:

(*Continued*)

								Under USD 50,000: 17; USD 50,000 to 99,999: 58; ≥ USD 100,000: 25
Quattrin 2012	I: family-based intervention	12 months (2 years)	Age 2 to 5 years, BMI ≥ 85th percentile, parent with BMI ≥ 27	2008 to 2013	USA	Primary care	Non-Hispanic white: 71. 7 Non-Hispanic black: 15.2 Hispanic: 10.9 Asian: 2.2 Other: 0	Yearly family income: USD 65,729 ± 30,061 with 8.3% of the households reporting a yearly income < USD 20,000
	C: information control						Non-Hispanic white: 74 Non-Hispanic black: 8 Hispanic: 8 Asian: 0 Other: 10	
Bocca 2012	I: multidisciplinary programme	16 weeks (3 years)	Age 3 to 5 years, overweight or obese (International Obesity Task Force)	2006 to 2008	The Netherlands	Outpatient clinic	-	-
	C: usual care							
Taveras 2011	I: High Five for Kids: behavioural intervention	2 years: 12 months intensive, 12 months maintenance (12 months, 2 years not currently reported)	Age 2 to 6.9 years, BMI ≥ 95th percentile or BMI 85th to 95th percentile if ≥ 1 parent was overweight (BMI ≥ 25)	-	USA	Primary care paediatric offices	White: 47 Black: 28 Latino: 19 Other: 7	Parent educational attainment, college or below: 42; college graduate: 58 Household income, %: ≤ USD 50,000: 36; ≥ USD 50,001: 64

(*Continued*)

	C: usual care						White: 70 Black: 7 Latino: 14 Other: 9	Parent educational attainment, college or below: 34; college graduate: 66 Household income, %: ≤ USD 50, 000: 20; ≥ USD 50, 001: 80
Stark 2011	I: LAUNCH	6 months (12 months)	Age 2 to 5 years, BMI ≥ 95th percentile but ≤ 100% above the mean BMI, parent with BMI ≥ 25	2008 to 2009	USA	Hospital	White: 75 Hispanic: 25	Hollingshead classification 3.6 (0.7); Income, USD (%): 0 to 49,999: 0; 50,000 to 74,999: 25; 75,000 to 99,999: 38; 100, 000 to 124, 999: 25; 125,000 to 149,999: 13
	C: enhanced standard care						White: 90 Hispanic: 10	Hollingshead classification 4.2 (0.4); Income, USD (%): 0 to 49,999: 20; 50,000 to 74,999: 0; 75,000 to 99,999: 50; 100, 000 to 124,

(*Continued*)

								999: 30; 125,000 to 149,999: 0
Lanigan 2010	I:Trim Tots	6 months (2 years) (6 months' follow-up reported only)	Aged 1 to 5 years, BMI ≥ 91st percentile	2008 to 2012	UK	Community	White: 83	Social class % non-manual: 45; % no qualifications: 10; % university degree: 16
	C: wait-list control						White: 82	Social class % non-manual: 51; % no qualifications: 12; % university degree: 18
Kelishadi 2009	I1: dairy-rich diet	6 months (3 years)	Preschool, BMI ≥ 95th percentile age and sex-specific	2003 to 2006	Iran	Obesity research clinic	-	-
	I2: energy-restricted diet							
	C: control							

- denotes not reported
BMI: body mass index; C: comparator; I: intervention; LAUNCH: Learning about Activity and Understanding Nutrition for Child Health; SD: standard deviation

Appendix 4. Baseline characteristics (II)

	Intervention(s) and comparator (s)	**Sex [female %]**	**Age [mean (SD)]**	**BMI [mean kg/ m² (SD)]**	**Body weight [mean kg (SD)]**	**Parental weight / BMI**	**Comedications / Cointerventions**	**Comorbidities**
Stark 2014	I1: LAUNCH home visits	80	4.7 (1.3)	BMI z score: 2.1 (0.2)	24.6 (4.8)	-	-	-

(*Continued*)

	I2: LAUNCH clinic visits	64	4.2 (1.1)	BMI z score: 2.5 (0.8)	26.6 (8.9)	-	-	-
	C: enhanced usual care	67	4.8 (0.7)	BMI z score: 2.4 (0.4)	26.1 (5.7)	-	-	-
Quattrin 2012	I: family-based intervention	68	4.6 (1.4)	20.4 (3.4) BMI z score: 2.2 (0.8) BMI %: 32.4 (22.4)	24.8 (6.8)	BMI: 37.2 (56.3)	-	-
	C: information control	66	4.4 (1.4)	20.1 (2.8) BMI z score: 2.1 (0.7) BMI %: 29.8 (17.1)	23.5 (5.7)	BMI: 36.2 (48.8)	-	-
Bocca 2012	I: multidisciplinary programme	70	4.6 (0.8)	21.2 (2.9) BMI z score 2.7 (1.0)	28.4 (6.3)	-	-	-
	C: usual care	74	4.7 (0.8)	21.0 (2.7) BMI z score: 2.7 (1.0)	28.1 (6.8)	-	-	-
Taveras 2011	I: High Five for Kids: behavioural intervention	48	4.8 (1.2)	19.2 (2.6) BMI z score: 1.9 (0.7)	-	BMI < 25, %: 3 BMI 25 to 30, %: 36 BMI ≥ 30, %: 61	-	-
	C: usual care	49	5.2 (1.1)	19.1 (2.0) BMI z score: 1.8 (0.6)	-	BMI < 25, %: 5 BMI 25 to 30, %: 52 BMI ≥ 30, %: 44	-	-
Stark 2011	I: LAUNCH	25	4.4 (0.9)	BMI percentile: 99 (1)	-	-	-	-
	C: enhanced standard care	40	3.9 (1.1)	BMI percentile: 98 (3)	-	-	-	-

(*Continued*)

Lanigan 2010	I: Trim Tots	43	2.5 (1.0)	18 (1.8) BMI z score: 1.0 (0.9)	15.2 (3.6)	-	-	-
	C: wait-list control	62	2.3 (1.0)	19.1 (17) BMI z score: 1.6 (0.9)	15.7 (4.1)	-	-	-
Kelishadi 2009	I1: dairy-rich diet	-	5.4 (0.2)	22.1 (0.9) BM z score: 2.4 (0.01)	-	-	-	-
	I2: energy-restricted diet	-	5.5 (0.7)	22.7 (0.8) BM z score: 2.3 (0.04)	-	-	-	-
	C: control	-	5.7 (0.3)	22.4 (0.5) BM z score: 2.4 (0.01)	-	-	-	-

- denotes not reported
BMI: body mass index; C: comparator; I: intervention; LAUNCH: Learning about Activity and Understanding Nutrition for Child Health; SD: standard deviation

Appendix 5. Matrix of study endpoints (publications and trial documents)

	Endpoints quoted in trial document(s) (ClinicalTrials.gov, FDA/EMA document, manufacturer's website, published design paper)[a]	**Study results posted in trial register [Yes/No]**	**Endpoints quoted in publication(s)**[b]	**Endpoints quoted in abstract of publication(s)**[b,c]
Stark 2014	**Source:** NCT01419951 **Primary outcome measure(s)**: change in BMI z score	No (last verified: October 2014) History of changes: 5 documented changes	**Primary outcome measure(s)**: child and parent weight and height to calculate BMI z score and BMI	**Primary outcome measure(s)**: change in BMI z score
	Secondary outcome measure(s): change in parent weight loss, change in child caloric intake, change in home food and activity environment,		**Secondary outcome measure(s)**: caloric intake, improvements in the home environment, change in physical activity, parenting styles and dimensions (ex-	**Secondary outcome measure(s)**: -

(*Continued*)

	change in child physical activity, change in parent-child mealtime interactions, change in health-related quality of life		ploratory outcome), Child Feeding Questionnaire (exploratory outcome)	
	Other outcome measure (s): -		**Other outcome measure (s)**: -	**Other outcome measure (s)**: -
Quattrin 2012	**Source:** NCT01029834 **Primary outcome measure(s)**: per cent BMI overweight for child and parent	No (last verified: December 2014) History of changes: 3 documented changes	**Primary outcome measure(s)**: BMI per cent	**Primary outcome measure(s)**: BMI per cent
	Secondary outcome measure(s): reduction in number of sugared drinks, high-energy food, and sedentary activities. Increase in fruits, vegetables, and physical activity		**Secondary outcome measure(s)**: BMI z score; weight; height; parental BMI; parental weight	**Secondary outcome measure(s)**: BMI z score, parental BMI
	Other outcome measure (s): -		**Other outcome measure (s)**: -	**Other outcome measure (s)**:
Bocca 2012	**Source:** NTR872 **Primary outcome measure(s)**: difference in progression of BMI between both groups	No (last verified: February 2007) History of changes: -	**Primary outcome measure(s)**: weight reduction, change in BMI z score, BMI, body fat percentage, visceral fat	**Primary outcome measure(s)**: change in BMI, BMI z score, visceral fat
	Secondary outcome measure(s): dietary intake, physical activity, behavioural modification, body composition, fat distribution, metabolic syndrome, insulin resistance, blood lipid profile, inflammatory markers, quality of life		**Secondary outcome measure(s)**: abdominal subcutaneous fat, waist circumference z score, hip circumference z score, upper arm circumference, and fat-free mass	**Secondary outcome measure(s)**: visceral fat, waist circumference z score
	Other outcome measure (s): -		**Other outcome measure (s)**: -	**Other outcome measure (s)**: waist circumference, HRQoL

(*Continued*)

Taveras 2011	**Source:** NCT00377767 **Primary outcome measure(s)**: BMI	No (last verified: September 2006) History of changes: no documented changes	**Primary outcome measure(s)**: change in BMI	**Primary outcome measure(s)**: BMI
	Secondary outcome measure(s): television viewing behaviours, sugar-sweetened beverages intake, fast-food intake		**Secondary outcome measure(s)**: TV watching, intake of sugar-sweetened beverages, fast-food intake, fruit and vegetable intake, outdoor physical activity time, parental views of the intervention	**Secondary outcome measure(s)**: TV viewing, sugar-sweetened beverages intake, fast-food intake
	Other outcome measure (s): -		**Other outcome measure (s)**: -	**Other outcome measure (s)**: -
Stark 2011	**Source:** NCT01018121 **Primary outcome measure(s)**: BMI z score	No (last verified: November 2009) History of changes: 0 documented changes	**Primary outcome measure(s)**: child BMI z score, BMI percentile, parent BMI	**Primary outcome measure(s)**: change in BMI z score, BMI percentile, weight change, parent weight change
	Secondary outcome measure(s): parent weight loss, child caloric intake, home food and activity environment, child physical activity, parent-child mealtime interactions		**Secondary outcome measure(s)**: child caloric intake, changes in the home food environment, child's physical activity	**Secondary outcome measure(s)**: -
	Other outcome measure (s): -		**Other outcome measure (s)**: parenting styles, children's eating and family mealtime interactions, parental child-feeding attitudes and practices, HRQoL, parent motivation for treatment, barriers to participation, satisfaction with treatment content and ability to make the recommended change	**Other outcome measure (s)**: -
Lanigan 2010	**Source:** NCT00675662 **Primary outcome measure(s)**: BMI	No (last verified: September 2015) History of changes: 1 documented change	**Primary outcome measure(s)**: BMI z score	**Primary outcome measure(s)**: BMI, BMI z score

(*Continued*)

	Secondary outcome measure(s): cardiovascular disease risk factors, physical activity (accelerometry), motor co-ordination, behaviour (general and dietary), cardiovascular fitness, waist circumference		**Secondary outcome measure(s)**: -	**Secondary outcome measure(s)**: -
	Other outcome measure (s): -		**Other outcome measure (s)**: -	**Other outcome measure (s)**: -
Kelishadi 2009	**Source:** unable to locate **Primary outcome measure(s)**: -	Unable to locate	**Not specified as primary or secondary:** BMI z score, waist circumference, per cent body fat, energy intake, blood pressure, fasting blood sugar, total cholesterol, HDL cholesterol, triglycerides, LDL cholesterol, plasma insulin, insulin resistance, metabolic syndrome	BMI z score, waist circumference, serum triglycerides, insulin levels, HDL cholesterol, insulin resistance, energy expenditure, blood pressure
	Secondary outcome measure(s): -			
	Other outcome measure (s): -			

- denotes not reported

[a] Trial document(s) refers to all available information from published design papers and sources other than regular publications (e.g. FDA/EMA documents, manufacturer's websites, trial registers)

[b] Publication(s) refers to trial information published in scientific journals (primary reference, duplicate publications, companion documents or multiple reports of a primary study)

BMI: body mass index; EMA: European Medicines Agency; FDA: Food and Drug Administration (US); HDL: high-density lipoprotein; HRQoL: health-related quality of life; LDL: low-density lipoprotein

[c] Other outcome measures refer to all outcomes not specified as primary or secondary outcome measures

Appendix 6. Examination of outcome reporting bias according to ORBIT classification

	Outcome	High risk of bias (category A)[a]	High risk of bias (category D)[b]	High risk of bias (category E)[c]	High risk of bias (category G)[d]
Stark 2014	N/A				
Quattrin 2012					
Bocca 2012					

(*Continued*)

Taveras 2011					
Stark 2011					
Lanigan 2010					
Kalishadi 2009					

[a] Clear that outcome was measured and analysed; trial report states that outcome was analysed but only reports that result was not significant.
(Classification 'A', table 2, Kirkham 2010)
[b] Clear that outcome was measured and analysed; trial report states that outcome was analysed but no results reported.
(Classification 'D', table 2, Kirkham 2010).
[c] Clear that outcome was measured but not necessarily analysed; judgement says likely to have been analysed but not reported because of non-significant results.
(Classification 'E', table 2, Kirkham 2010)
[d] Unclear whether the outcome was measured; not mentioned, but clinical judgement says likely to have been measured and analysed but not reported on the basis of non-significant results.
(Classification 'G', table 2, Kirkham 2010)
N/A: not applicable; ORBIT: Outcome Reporting Bias in Trials

Appendix 7. Definition of endpoint measurement

	All-cause mortality	Behaviour change	Changes in BMI and body weight	Height	Health-related quality of life	Morbidity Socioeconomic effects	Parent-child relationship or assessment of parenting	Participant views of the intervention	Severe/ serious adverse events
Stark 2014	N/I	Children's physical activity measured by the GT1M accelerometer, validated and calibrated for use with preschool children	Measured in triplicate following standard anthropometric procedures by trained personnel. Children's BMI z score and BMI per-	Child and parent height measured in triplicate following standard anthropometric procedures	N/I	N/I	Child Feeding Questionnaire, a 31-item questionnaire assessing parental child-feeding attitudes and practices. 2 subscales	N/I	N/I

(*Continued*)

		(references provided). Worn for 7 days, with a minimum of 3 days of data required for inclusion in analysis. A valid day was defined as 5 hours of wear time. Average daily minutes of moderate and vigorous activity (MVPA) were calculated	centile for sex and age calculated using the CDC growth curves				used, Restriction and Pressure to Eat, that have been linked with child eating and weight status. Rated items on a 5-point Likert-type scale ("disagree" to "agree") with higher scores indicating higher endorsement		
Quattrin 2012	N/I	N/I	Weight measured by a trained research assistant every session in both groups using an electronic scale calibrated before each assessment, and research assistants followed a standardised protocol	Height using a stadiometer, calibrated before each assessment, and research assistants followed a standardised protocol	N/I	N/I	N/I	N/I	N/I

(*Continued*)

Bocca 2012	N/I	Physical activity measured using a pedometer (reference provided) worn at least 3 weekdays and 1 weekend day, parents documented the amount of steps in a diary each day. Average number of steps per day calculated	All anthropometric measurements done in duplicate and averaged, children only wearing underwear. Standard calibrated scales to determine weight to the nearest 0.05 kg. Waist circumference measured to nearest 0.1 cm in orthostatic position at midpoint between lateral iliac crest and lowest rib using a standard measuring tape. Hip circumference measured to nearest 0.1 cm at level of greater trochanter of both femurs, standing	Standard calibrated stadiometers were used to determine height to the nearest 0.1 cm	Dutch Child AZL TNO Quality-of-Life (DUX-25) questionnaire; Dutch edition of the Child Health Questionnaire Parent Form (CHQ-PF50)	N/I	N/I	N/I	N/I

(*Continued*)

			upright. Right upper arm circumference measured to nearest 0.1 cm at middle of the upper arm. BMI-z, WC-z, and HC-z calculated using web-based program Growth Analyzer version 3, which contains age-specific and sex-specific data from the Fourth Dutch Growth Study 1996 and 1997 (reference provided). Visceral fat and abdominal subcutaneous fat measured using 50 kHz fixed-frequency bioimpedan analyser (reference provided)						

(*Continued*)

			. Resistance and reactance values collected, corresponding to total body water and extracellular water content, respectively. All measurements performed 3 times and averaged. Fat-free mass and BF% determined (reference provided) . Abdominal SCF and VF were estimated based on distance measurements by standard protocol using a manual ultrasound device (reference provided) . Measurements performed at the						

(*Continued*)

			middle of imaginary line between both midpoints between lateral iliac crest and lowest rib. All measurements were performed twice and to nearest 0.01 cm and averaged. Subcutaneous fat measured at a depth of 4.7 cm with the transducer in a transverse position. Distance between skin and abdominal muscles measured on a frozen image after maximum decompression by lifting the transducer and after the child exhaled. Visceral fat measured at a depth						

(*Continued*)

			of 14 cm with the transducer in a longitudinal position. After the aorta and lumbar spine were visualised, distance between the peritoneum and lumbar spine measured on a frozen image after maximal decompression and exhalation						
Taveras 2011	N/I	Daily television and video viewing, using previously validated questions (reference given) , daily sugar-sweetened beverage intake using questions from a validated semi-quantitative child food	All medical assistants in intervention and usual care practices were trained on conducting research-standard anthropometric measurements. Children's weight measured without shoes, using an electronic,	Height using a stadiometer	N/I	N/I	N/I	Intervention group only: asked parents to rate how satisfied they were with the program and if they would recommend the program to their family or friends and whether they had chosen to work on	N/I

(*Continued*)

		frequency questionnaire (reference given), daily fruit and vegetable intake (reference provided), outdoor physical activity time (reference provided)	calibrated scale (reference given)					specific behaviours	
Stark 2011	N/I	Children's physical activity was measured by the MTI actigraph which has been validated and calibrated for use with preschool children, worn for 7 days	Child and parent weight measured in triplicate following standard anthropometric procedures. Children's BMI z score and BMI percentile for sex and age were calculated using the CDC growth curves. Adult BMI was calculated as kg/m²	Child and parent height measured in triplicate following standard anthropometric procedures	The PedsQL Generic Core Scales	N/I	Child Feeding Questionnaire, a 31-item questionnaire assessing parental child-feeding attitudes and practices. 2 subscales used, Restriction and Pressure to Eat. Items rated on a 5-point Likert-type scale ("disagree" to "agree")	Barrier to Treatment Participation Scale, a 58-item questionnaire assessing barriers to participation in outpatient treatment, which was administered at month 6 to assess: (i) stressors and obstacles that compete with treatment, (ii) treatment demands and issues, and (iii)	N/I

(*Continued*)

								perceived relevance of treatment Treatment Satisfaction Questionnaireto measure satisfaction with treatment content and ability to make the recommended changes rated using a 5-point Likert scale ("extremely unsatisfied" to "extremely satisfied")	
Lanigan 2010	N/I	Physical activity (accelerometer)	BMI z score, waist circumference (methods not described)	N/I	N/I	N/I	N/I	N/I	N/I
Kelishadi 2009	N/I	Physical activity pattern assessed by validated questionnaire (reference provided): 9 different MET levels were	Weight measured by a calibrated scale (reference provided) to the nearest 0.1 kg with participants	Height measured by a calibrated stadiometer (reference provided) to the nearest 0.1 cm	N/I	N/I	N/I	N/I	N/I

(*Continued*)

		ranged on a scale from sleep/ rest (0.9 METs) to high- intensity physical activities (> 6 METs) . For each activity level, the MET value was multiplied by the time spent at that particular level. The MET time at each level was added to obtain a total over 24- hour MET time, representing the physical activity level on an average weekday. Energy expenditure was estimated by multiplying the total 24- hour MET time by the body weight	lightly clothed and barefoot. BMI was calculated according to 2002 CDC growth charts (reference provided) . LMS method used to calculate BMI z score as the measurement of degree of overweight (reference provided) . Waist circumference measured at a point midway between the lower border of the ribcage and the iliac crest at the end of normal expiration. Percentage of body fat determined using dual-energy absorp-						

(*Continued*)

			tiometry (reference provided) . All measurements were made by same trained general physician and under supervision of same paediatrician						

BF%: body fat percentage; BMI: body mass index; BMI-z: body mass index z score; CDC: Centers for Disease Control and Prevention; HC-z: hip circumference z score; MET: metabolic equivalent; N/D: not defined; N/I: not investigated; PedsQL: Pediatric Quality of Life Inventory; SCF: subcutaneous fat; VF: visceral fat; WC-z: waist circumference z score

Appendix 8. Adverse events

	Intervention(s) and comparator(s)	**Participants included in analysis [N]**	**Deaths [N (%)]**	**Participants with adverse events [N (%)]**	**Participants with severe/serious adverse events [N (%)]**	**Participants discontinuing study due to adverse events [N (%)]**	**Participants hospitalised due to adverse events [N (%)]**	**Participants with outpatient treatment due to adverse events [N (%)]**	**Participants with specific events [description] [N (%)]**
Stark 2014	I1: LAUNCH home visits	-	-	-	-	-	-	-	-
	I2: LAUNCH clinic visits	-	-	-	-	-	-	-	-
	C: enhanced usual care	-	-	-	-	-	-	-	-
Quattrin 2012	I: family-based intervention	-	-	-	-	-	-	-	-

(*Continued*)

	C: information control	-	-	-	-	-	-	-	-
Bocca 2012	I: multidisciplinary programme	-	-	-	-	-	-	-	-
	C: usual care	-	-	-	-	-	-	-	-
Taveras 2011	I: High Five for Kids: behavioural intervention	-	-	-	-	-	-	-	-
	C: usual care	-	-	-	-	-	-	-	-
Stark 2011	I: LAUNCH	-	-	-	-	-	-	-	-
	C: enhanced standard care	-	-	-	-	-	-	-	-
Lanigan 2010	I: Trim Tots	49	-	-	0	0	-	-	-
	C: wait-list control	39	-	-	0	0	-	-	-
Kelishadi 2009	I1: dairy-rich diet	-	-	-	-	-	-	-	-
	I2: energy-restricted diet	-	-	-	-	-	-	-	-
	C: control	-	-	-	-	-	-	-	-

- denotes not reported
C: comparator; I: intervention; LAUNCH: Learning about Activity and Understanding Nutrition for Child Health

Appendix 9. Checklist to aid consistency and reproducibility of GRADE assessments

		Multicomponent intervention versus control		Dietary interventions versus control
		BMI z score	**Health-related quality of life**	**BMI**
Study limitations (risk of bias)[a]	1. Was random sequence generation used (i.e. no potential for selection bias)?	Yes	Yes	Yes
	2. Was allocation concealment used (i.e. no potential for selection bias)?	Unclear	Unclear	Unclear
	3. Was there blinding of participants and personnel (i.e. no potential for performance bias)?	Unclear	No ()	Unclear
	4. Was there blinding of outcome assessment (i.e. no potential for detection bias)?	Yes	No ()	Yes
	5. Was an objective outcome used?	Yes	No ()	Yes
	6. Were more than 80% of participants enrolled in trials included in the analysis (i.e. no potential reporting bias)?[e]	No ()	No ()	Yes
	7. Were data reported consistently for the outcome of interest (i.e. no potential selective reporting)?	No ()	No ()	No ()
	8. No other biases reported (i.e. no potential of other bias)?	Unclear	Unclear	Unclear
	9. Did the trials end up as scheduled (i.e. not stopped early)?	No (1 of 6 trials stopped early) ()	Yes	Yes

(*Continued*)

Inconsistency[b]	1. Point estimates did not vary widely?	Yes		
	2. To what extent did confidence intervals overlap (substantial: all confidence intervals overlap at least one of the included studies point estimate; some: confidence intervals overlap but not all overlap at least one point estimate; no: at least one outlier: where the confidence interval of some of the studies do not overlap with those of most included studies)?	Some		
	3. Was the direction of effect consistent?	Yes	Yes	
	4. What was the magnitude of statistical heterogeneity (as measured by I^2): low ($I^2 < 40\%$), moderate (I^2 40% to 60%), high $I^2 > 60\%$)?	Low (end of intervention) Moderate (follow-up)		
	5. Was the test for heterogeneity statistically significant ($P < 0.1$)?	Not statistically significant (end of intervention and follow-up)		
Indirectness[a]	1. Were the populations in included studies applicable to the decision context?	Highly applicable	Highly applicable	Highly applicable
	2. Were the interventions in the included studies applicable to the decision context?	Highly applicable	Highly applicable	Highly applicable
	3. Was the included outcome a surrogate outcome?	Yes ()	No	Yes

(*Continued*)

	4. Was the outcome time frame sufficient?	Sufficient	Sufficient	Sufficient
	5. Were the conclusions based on direct comparisons?	Yes	Yes	Yes
Imprecision[c]	1. Was the confidence interval for the pooled estimate consistent with benefit?	Yes		Yes
	2. What is the magnitude of the median sample size (high: 300 participants, intermediate: 100 to 300 participants, low: < 100 participants)?[e]	Low ()	Low ()	Low ()
	3. What was the magnitude of the number of included studies (large: > 10 studies, moderate: 5 to 10 studies, small: < 5 studies)?[e]	Small ()	Small ()	Small ()
	4. Was the outcome a common event (e.g. occurs more than 1/100)?	Not applicable	Not applicable	Not applicable
Publication bias[d]	1. Was a comprehensive search conducted?	Yes	Yes	Yes
	2. Was grey literature searched?	Yes	Yes	Yes
	3. Were no restrictions applied to study selection on the basis of language?	Yes	Yes	Yes
	4. There was no industry influence on studies included in the review?	Yes	Yes	Yes
	5. There was no evidence of funnel plot asymmetry?	Unclear	Unclear	Unclear

(*Continued*)

	6. There was no discrepancy in findings between published and unpublished trials?	Unclear	Unclear	Unclear

[a] Questions on risk of bias are answered in relation to the majority of the aggregated evidence in the meta-analysis rather than to individual trials.
[b] Questions on inconsistency are primarily based on visual assessment of forest plots, and the statistical quantification of heterogeneity is based on I^2
[c] When judging the width of the confidence interval, it is recommended to use a clinical decision threshold to assess whether the imprecision is clinically meaningful.
[d] Questions address comprehensiveness of the search strategy, industry influence, funnel plot asymmetry, and discrepancies between published and unpublished trials.
[e] Depends on the context of the systematic review area.
(): key item for possible downgrading the quality of the evidence (GRADE) as shown in the footnotes of the 'Summary of findings' table(s); BMI: body mass index; GRADE: Grading of Recommendations Assessment, Development and Evaluation

Appendix 10. Survey of study investigators providing information on included trials

	Date trial author contacted	**Date trial author replied**	**Date trial author was asked for additional information [short summary]**	**Date trial author provided data [short summary]**
Stark 2014	2 October 2015	2 October 2015	5 October 2015 Allocation concealment approach, details of blinding, selective reporting of outcomes, physical activity data (reported narratively only)	17 October 2015 Allocation concealment approach, details of blinding, selective reporting of outcomes, physical activity data
Quattrin 2012	2 October 2015	2 October 2015	5 October 2015 Data (presented in figures only), allocation concealment approach, selective reporting of outcomes, reasons for differences between 2012 and 2014 publications	No information
Bocca 2012	2 October 2015	No reply	N/A	N/A
Taveras 2011	2 October 2015	No reply	N/A	N/A

(*Continued*)

Stark 2011	2 October 2015	2 October 2015	5 October 2015 Allocation concealment approach, details of blinding, data for secondary outcomes not published (e.g. health-related quality of life, parent weight loss)	17 October 2015 Allocation concealment approach, details of blinding, data for health-related quality of life, parent weight loss
Lanigan 2010	2 October 2015	2 October 2015	5 October 2015 Change from baseline data (all outcomes), allocation concealment approach, details of blinding, attrition, selective reporting of outcomes	2 November 2015 Allocation concealment approach, details of blinding, flow diagram, 6-month change data for BMI, BMI z score, weight, waist circumference
Kelishadi 2009	2 October 2015	2 October 2015	5 October 2015 Data (presented in figures only), allocation concealment approach, details of blinding, selective reporting of outcomes	No information

BMI: body mass index; N/A: not applicable

Appendix 11. Health-related quality of life: instruments

	Name [type of measurement]	Dimensions (subscales) [no. of items]	Validated instrument	Answer options	Scores	Direction of scales	Minimal important difference
Stark 2014	PedsQL (parent version)	-	Yes	-	-	Higher scores indicate better quality of life	-
Bocca 2012	Dutch Child AZL TNO/ DUX-25 Questionnaire for Preschool Children's Quality of Life, measures daily ac-	25 questions on 4 domains: physical, emotional, home, and social	Yes	Using 1 of 5 abstract faces, from happy (score 5) to sad (score 1), giving a 5-point Likert scale (completed by	Domain scores are calculated by adding all the single-item scores, which can then be converted to a 0 to 100 scale	Higher score indicating a better quality of life	-

(*Continued*)

	tivities			the parent)			
	Dutch edition of the Child Health Questionnaire Parent Form (CHQ-PF50), measures health perception	50 items, divided into 11 multiscales and 4 single-item questions addressing the child's physical, emotional, and social well-being. Each CHQ scale has 3 to 6 items	Yes	4 to 6 possible responses per item	Total scores for each scale transformed into a score ranging from 0 to 100	Higher score indicating a better quality of life	-
Stark 2011	The PedsQL Generic Core Scales	Total Score (23 items) and the Physical Functioning (8 items), Emotional Functioning (5 items), and Social Functioning (5 items) subscales used only	Yes	5-point scale ("never a problem" to "almost always a problem")	0 to 4 raw scores to 0 to 100 as follows: 0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0 Scale scores: the mean is computed as the sum of the items over the number of items answered Total scale score: the mean is computed as the sum of all the items over the number of items answered on all the scales	Higher scores indicate better quality of life	-

- denotes not reported
PedsQL: Pediatric Quality of Life Inventory

WHAT'S NEW

Last assessed as up-to-date: 10 March 2015.

Date	Event	Description
17 February 2016	New citation required and conclusions have changed	Given the rapid growth in the treatment of child and adolescent obesity, we have split the original review ('Interventions for treating obesity in children and adolescents') into six separate reviews, with a specific intervention and age focus: (1) Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years; (2) Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in schoolchildren from the age of 6 to 11 years; (3) Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years; (4) Drug interventions for the treatment of obesity in children and adolescents; (5) Parent-only interventions for childhood overweight or obesity; (6) Surgery for the treatment of obesity in children and adolescents
17 February 2016	New search has been performed	This is an update of the former Cochrane review 'Interventions for treating obesity in children and adolescents

HISTORY

Review first published: Issue 3, 2016

Date	Event	Description
11 October 2008	New citation required and conclusions have changed	This review concludes that combined behavioural lifestyle interventions compared to standard care or self help can produce a significant and clinically meaningful reduction in overweight in children and adolescents The search was updated to May 2008. Some amendments were made to update the search strategies. No changes have been made to other aspects of the methodology. We have included 46 new studies, among which contained information on drug interventions for treating obesity in adolescents. The added evidence suggests that lifestyle interventions appear to have positive effects

(*Continued*)

		in the treatment of child and adolescent obesity. Furthermore, orlistat and sibutramine were found to have beneficial effects on adiposity in obese adolescents. However, a range of adverse effects were noted
3 July 2008	Amended	Converted to new review format. Authorship changed with new authors and new contact person

CONTRIBUTIONS OF AUTHORS

Jill Colquitt (JC): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft, and future review updates.

Emma Loveman (EL): acquiring trial reports, trial selection, data extraction.

Claire O'Malley (COM): acquiring trial reports, trial selection, data extraction.

Liane Azevedo (LA): acquiring trial reports, trial selection, data extraction.

Emma Mead (EM): acquiring trial reports, trial selection, data abstraction.

Lena Al-Khudairy (LAl-K): acquiring trial reports, trial selection.

Louisa J Ells (LE): acquiring trial reports, trial selection.

Maria-Inti Metzendorf (MIM): search strategy development, review draft.

Karen Rees (KR): oversaw the conduct of the review, acquiring trial reports, trial selection, data abstraction, acted as third review author, review draft, and future review updates.

DECLARATIONS OF INTEREST

JC: none known.

EL: none known.

COM: none known.

LA: none known.

EM: none known.

LAl-K: none known.

LE: none known.

MIM: none known.

KR: none known.

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- Health and Social Care Institute, Teeside University, UK.
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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Given the rapid growth in the treatment of child and adolescent obesity, the original review has now been split into six separate reviews, with a specific intervention and age focus.

1. Diet, physical activity. and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years.

2. Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in schoolchildren from the age of 6 to 11 years.

3. Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.

4. Drug interventions for the treatment of obesity in children and adolescents.

5. Parent-only interventions for childhood overweight or obesity.

6. Surgery for the treatment of obesity in children and adolescents.

For lifestyle interventions, we included only randomised controlled trials that were specifically designed to treat obesity in children and observed participants for a minimum of six months. The rationale for introducing this criterion arose from the belief that many interventions appear to be effective in the short term (up to three months), but not in the long term (Glenny 1997). It seemed to be more important to evaluate the longer-term effects of treatments, as this would provide a more valuable indication of effectiveness, given the chronic nature of obesity.

NOTES

Part of the Background, the Methods section, Appendices, Additional tables, and Figures 1 to 3 of this review are based on a standard template established by the Cochrane Metabolic and Endocrine Disorders Group.